mythic 18

Orphée SA

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REVISIONS

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02	22/06/04	HC	> V 0.5x	All sections modified
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04	10/09/04	HC	> V 0.6.0	Sections 4.1/9.5/8.5.1 modified
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06	08/10/04	HC	> V0.6.6	Sections 5.7
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11	05/03/07	HC	> V2.0	Add USB key management in sections 5.10/6/7 Printer management section 3/3.4
12	15/10/08	HC	> V3.0	All pages for new color screen

CONTACT ADDRESS

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LOCAL AGENT

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READ THIS BEFORE USING THE EQUIPMENT

	WARNING! RISK OF DANGER! Indicates a procedure to be strictly respected in order to avoid any risks for the operator (user) or damages on the instrument or on the quality of results.
	Indicates that wearing gloves is mandatory before performing the described operation due to risk of contact with materials that may be infectious.
NOTA	**Indicates important additional information**

DANGER

Misuse of electrical equipment may cause electrocution, burns, fire and other hazards.

⇨ Check that the voltage setting matches the supply voltage.
⇨ Protective earthing is required; plug the **MYTHIC 18** into a supply outlet which has an earth connection.
⇨ Preserve a good access to the supply outlet to be able to unplug the MYTHIC 18 in emergency case.
⇨ Do not place the power supply adapter in liquid, nor put it where it could fall into liquid. If the power supply adapter becomes wet, unplug it before touching it.
⇨ Do not use the **MYTHIC 18** if it is not working properly, or if it has suffered any damage (damage to the supply cord or its plug; damaged caused by dropping the power supply adapter).
⇨ Do not let the power supply adapter or its flexible cord come into contact with surfaces which are too hot to touch.
⇨ Do not place anything on top of the **MYTHIC 18**
⇨ Do not use the **MYTHIC 18** where aerosol sprays are being used, or where oxygen is being administered.
⇨ Do not use the **MYTHIC 18** out of doors
⇨ Always switch off the **MYTHIC 18** and disconnect the power adaptor before dismantling any part.

⇨ The **MYTHIC 18** is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories by an authorized people.

- Only human blood or artificial control blood should be run.
- Only the reagents mentioned in this manual are permitted to use.
- The optimum performances can be only achieved if the cleaning and maintenance procedures are carefully followed.

⇨ Due to the use of this equipment, all parts and surfaces of the **MYTHIC 18** are potentially infective. Wearing rubber gloves is highly recommended and after completion of work, washes hands with disinfectant.
⇨ Always replace or use parts of the equipment by parts supplied by ORPHEE distributor.
⇨ Basic safety precautions should always be taken. If the equipment is not used according to the manufacturer's instructions, the protective by the equipment may be impaired.
⇨ The treatment of waste and the elimination of a part or the complete instrument must be done in compliance with the local legislation.
⇨ Any output or input connections (except the printer and the barcode reader supplied by ORPHEE) cannot be done without the ORPHEE representative authorization.
⇨ Do not open the door located on the right side of the instrument (see section 1.1.3) when a hydraulic cycle is in progress for it would lead to an immediate stop. To re-start, shut the door and run a Control cycle (see section 9.3.1)

KEEP THESE INSTRUCTIONS

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This equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information listed below.

Guidance and manufacturer's declaration – Electromagnetic immunity

The MYTHIC 18 is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 18 should assure that it is used in such environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the MYTHIC 18, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150Khz to 80Mhz	3 Vrms	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vrms 80Mhz to 2,5Ghz	3 Vrms	$d = 1,2\sqrt{P}$ 80MHz to 800MHz $d = 2,3\sqrt{P}$ 800MHz to 2,5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80Mhz and 800MHz, the higher frequency range applies.

NOTE 2 Theses guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM an FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should considered. If the measured field strength in the location in which the MYTHIC 18 is used exceeds the applicable RF compliance level above, the MYTHIC 18 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MYTHIC 18.

[b] Over the frequency range 150KHz to 80MHz, field strengths should be less than 3V/m.

The symbol on the product indicates that this product may not be treated as household waste. Instead it shall be handed over the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information about recycling of this product, please contact your local city office or your distributor of this product.

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KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA

Name und Adresse der Firma
Nom et adresse de l'entreprise
Nome e indirizzo della ditta
Name and address of the firm

Orphée S.A.
19 Chemin du Champ des Filles
1228 Plan Les Ouates

Wir erklären in alleiniger Verantwortung, dass
Nous déclarons sous notre propre responsabilité que
Dichiariamo sotto nostra responsabilità che
We declare under our sole responsibility that

das Medizinprodukt für die In-vitro-Diagnostik
le dispositif médical de diagnostic in vitro
il dispositivo medico-diagnostico in vitro
the in vitro diagnostic medical device

Mythic 18

mit folgender Klassifizierung nach der Richtlinie über In-vitro-Diagnostika 98/79/EG
avec la classification selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE
con la classificazione secondo la direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE
classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC

☐ Produkt der Liste A, Anhang II / Dispositif de la liste A, annexe II / Dispositivo dell'elenco A, allegato II / Device of List A, Annex II
☐ Produkt der Liste B, Anhang II / Dispositif de la liste B, annexe II / Dispositivo dell'elenco B, allegato II / Device of List B, Annex II
☐ Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist / Dispositif destiné à l'autodiagnostic non listé dans l'annexe II / Dispositivo per test autodiagnostico non elencato nell'allegato II / Device for self-testing not listed in Annex II
☒ Sonstiges Produkt / Autre dispositif / Altro dispostivo / Other device

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.

remplit toutes les exigences de la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE qui le concernent.

soddisfa tutte le disposizioni della direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE che lo riguardano.

meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

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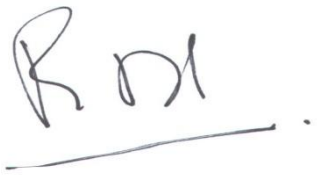
Angewandte Gemeinsame Technische Spezifikationen, harmonisierte Normen, nationale Normen oder andere normative Dokumente Spécifications techniques communes, normes harmonisées, normes nationales et autres documents normatifs appliqués Specifiche tecniche comuni, norme armonizzate o nazionali applicate, altri documenti normativi applicati Applied common technical specifications, harmonised standards, national standards or other normative documents	IEC 60601-1-2 (2001) EN 61000-3-2 EN 61000-3-3 EN 61000-4-2 (95) A1 (98) A2 (01) EN 61000-4-3 (02) EN 61000-4-4 (95) A1(01) EN 61000-4-5 A1 (01) EN 61000-4-6 (96) A1 (01) EN 61000-4-11 (94) A1 (01) EN 55011 Class B EN 55022 Class B IEC 61010-1 (2001) IEC 61010-2-081 (2001) IEC 61010-2-101 (2002)
Konformitätsbewertungsverfahren Procédure d'évaluation de la conformité Procedimentodi valutazionedellaconformità Conformity assessment procedure	Annex III
Konformitätsbewertungsstelle (falls beigezogen) Organe respons. de l'évaluat.de la conformité(si consulté) Organo incaric. della valutaz. della conform. (se consultato) Notified Body (if consulted)	N/A
Ort, Datum / Lieu, date / Luogo, data / Place, date	Name und Funktion / Nom et fonction /Nome e funzione / Name and function
Genève le 06 Juin 2008	



Philippe Daire
RA & QA

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1. INSTALLATION

1.1 UNPACKING

1.1.1 Introduction

The **MYTHIC 18** is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories by an authorized people.

- Only human blood or artificial control blood should be run.
- Only the reagents mentioned in this manual are permitted to use.
- The optimum performances can be only achieved if the cleaning and maintenance procedures are carefully followed.

If the MYTHIC 18 has been stored at a temperature less than 10°C, it must stay at room temperature during 24 hours before switching it on.

1.1.2 Unpacking Procedure

Before unpacking the instrument, we recommend to check the box of the instrument and notify any damage to the carrier.

- Open the box on the top, remove the starter kit.
- Remove the **MYTHIC 18** from the box.

Starter kit contents:

INSTALLATION KIT		
QTY	**Designation**	**Part Number**
1	M18 - DILUENT	005-1001-90 23
1	M18 - WASTE	005-1001-90 24
1	70W switching adapter	050-1001-01 70 24
1	European Power line cord	150-2001-CEE C13 1000
2	5/10-20L Adaptator	300-1009-05 1020
1	M18C User manual	605-1201-02
1	Screwdriver Slot 1/4"	700-7101-02

MAINTENANCE KIT		
QTY	**Designation**	**Part Number**
1	Tygon tubing L=1000mm 1.52x3.2mm	005-1001-90 016 032
1	Tygon tubing L=500mm 2.06x4mm	005-1001-90 020 040
1	Tubing 9	005-1001-90 09
1	Tubing 10	005-1001-90 10
5	Cables Ties	153-0101-100 25
2	O-ring Ø13.1x1.6 Fluocarbon 80SH	312-0505-1310 160
1	O-ring Ø1.4x1.25 Fluocarbon 80SH	312-0505-140 125 010
2	O-ring Ø5x1 Fluocarbon 80SH	312-0505-500 100
1	Silicon grease (3gr)	410-0501-02 02
1	Short Arm TORX T10 Tool	700-1101-10
1	Short Arm TORX T20 Tool	700-1101-20

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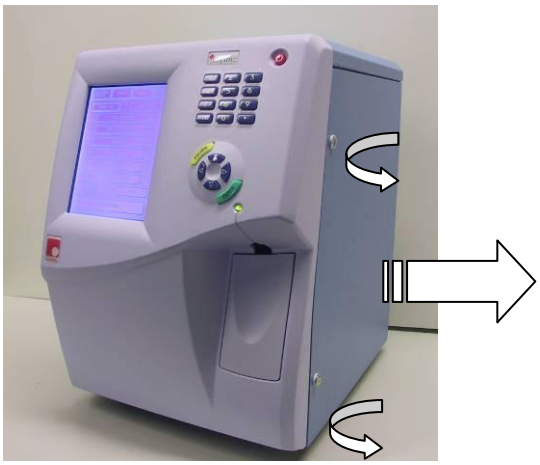
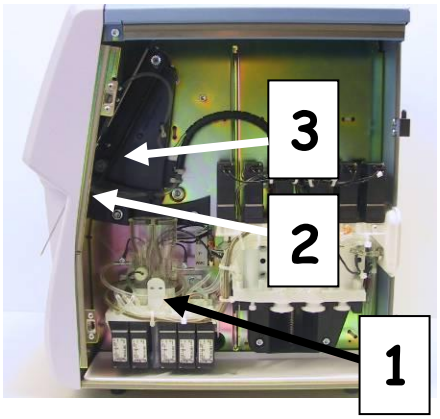
1.1.3 Visual checking



- Open the door on the right side with the key provided in the kit.



To be checked :

1- Counting chambers perfectly locked in their manifold locations.
2- Needle's dismountable system located in the rocker.
3- Rocker in front position at the maximum course.

	HAZARDOUS MOVING PARTS, BEWARE TO STAY AWAY FROM THESE PARTS WHEN THE MACHINE IS SWITCH ON.

1.2 INSTALLATION CONSTRAINTS

1.2.1 Installation place

To ensure that the **MYTHIC 18** fulfills its function, place the instrument on a table which supports the weight of the instrument, printer and reagents (around 40 Kg). Leave a space of 10 cm in the rear of the instrument to ensure a well-ventilated place. Avoid a place that can be exposed to direct sunlight.

1.2.2 Installation environment

a) Indoor use;
b) Altitude up to 2 000 m;
c) Temperature 18 °C to 32 °C;
d) Maximum relative humidity 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C;
e) MAINS supply voltage fluctuations up to ±10 % of the nominal voltage;
f) Transient over voltages typically present on the MAINS supply.
g) Rated pollution degree II.

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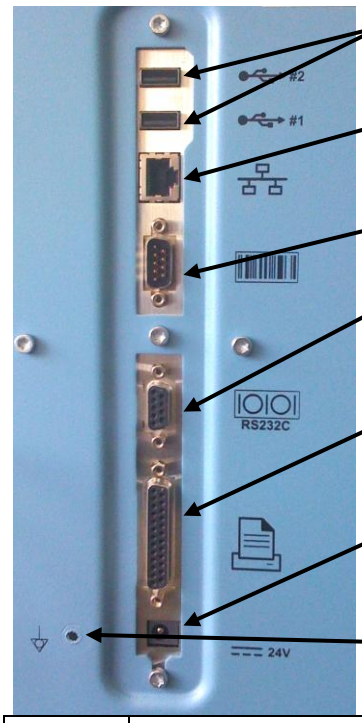
Please contact Orphée's representative if you want to use the instrument in special conditions (height higher than 2000 m or special power supply conditions).

1.3 ELECTRICAL CONNECTIONS

All the connectors are in the rear of the **MYTHIC 18**



CONNECTION : SYMBOL :

- 2 USB ports :
- Ethernet connection (TCP/IP) :
- External barcode reader (RS232C) :
- Host connection (RS232C) :
- Printer connection (Centronics) :
- Power supply cord connection : 24V-3A
- Equipotentiality :

	Any output or input connections (except the printer and the bar code reader supplied by ORPHEE) cannot be done without the ORPHEE representative authorization.

1.3.1 Power supply block

MYTHIC 18 must be connected to the power with the power supply block provided with the starter kit. Choose a well-ventilated place for the block and be sure to connect this power supply in a socket-outlet with a correct earth connection.

The power supply block must be placed at the rear of the **MYTHIC 18** and, if possible in an upper position to avoid the contact with any liquid.

To disconnect electrically the **MYTHIC 18**, remove the power supply plug from the main circuit.

	- In the case of replacement of the main power wire supplied with the MYTHIC 18 the new one must comply with the local regulation (3×1.5mm cable and 250V 10A plug). **- The MYTHIC 18 has been certified with the power supply box provided with the machine. The use of another external power supply box is not guaranteed. Please contact your Orphée's representative.**

1.4 PRINTER CONNECTION

Connect the printer cable in conformity with the printer user's manual.

Use the parallel rear plug of the **MYTHIC 18 (**) or the USB plug ( ) to connect the printer cable. Select the printer driver (section 3.3).

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1.5 CONNECTION, CHANGE AND PRIMING REAGENTS

MYTHIC 18 works with the reagents described in section 4.3. Some commercial reagents can also be used. Please contact your Orphée's representative.

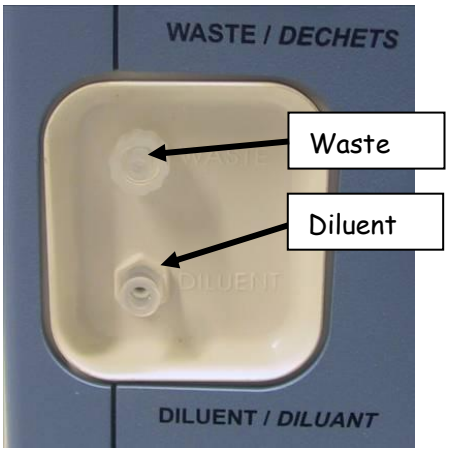
1.5.1 Connection

Lysis reagent and cleaning solution:

Before handling the reagents, read carefully their specifications described in section 4.3.

- Remove the door on the left side of the instrument.
- Put the reagent bottles in the dedicated location.
- Remove the caps of the bottles
- Tighten the yellow caps on the Lysis bottle (yellow sticker) and the blue one on the cleaning solution bottle (blue sticker).

Diluent and waste :



- Connect the diluent tube (male connector) on the outlet on the bottom and tighten the cap on the diluent container.
- To use a 20 liter diluent container adds the tubing straw adaptor supplied with the installation kit.
- Connect the waste tube (female connector) on the outlet on the top and tighten the cap on an empty container.

- **Do not modify the type and the length of the diluent and waste tubes.**
- **The diluent must be placed at the same level as the MYTHIC 18.**
- **Collect the waste in a container and treat it in compliance with your local legislation.**

Example of neutralization procedure usually used in a laboratory:
For 20 liters of waste produced by the **MYTHIC 18**, add 50 ml of a solution of sodium hydroxide (NaOH) at 200g/l, mix the container, add 100ml of bleach at 36° Chl, mix the container, wait one hour before empty it.

Only use this procedure if there is no specific local legislation for the treatment of the waste.

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1.5.2 Priming

When first starting the **MYTHIC 18**, it is necessary to perform a complete prime of the fluidic circuit.

	Before starting, be sure that all the reagent and waste tubes are properly connected.

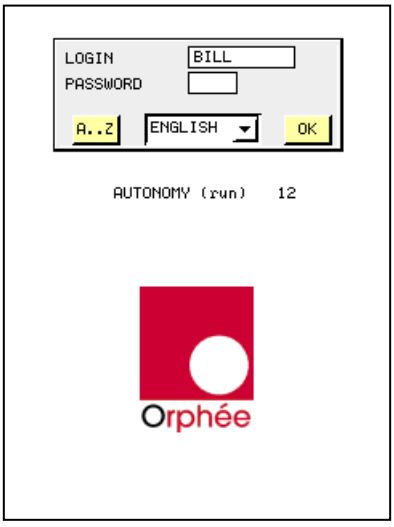
Priming procedure:

① Switch on:

- Connect the power supply block.
- Press the ON/OFF button.
- The cycle LED turns red. No cycle can be performed before it turns green.

- The information window could stay up to 3 mn to enable the update of all files.

② Login:



- The operator's identification display appears.
- Enter the user's identification, the password (see section 3.1) and press OK to validate.

- **AUTONOMY (run)** indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).

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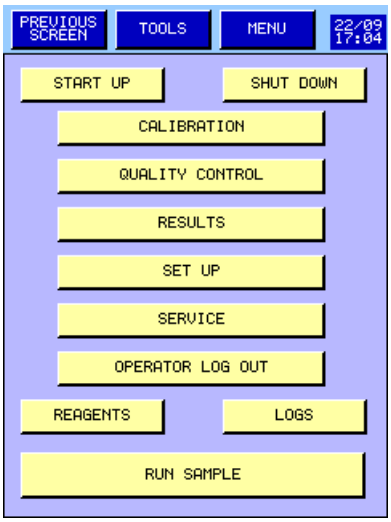
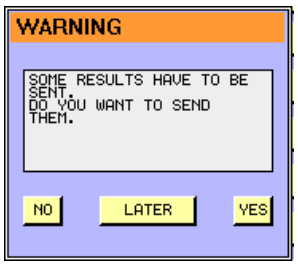
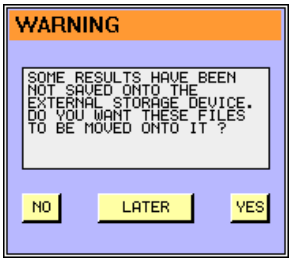


③ System priming:

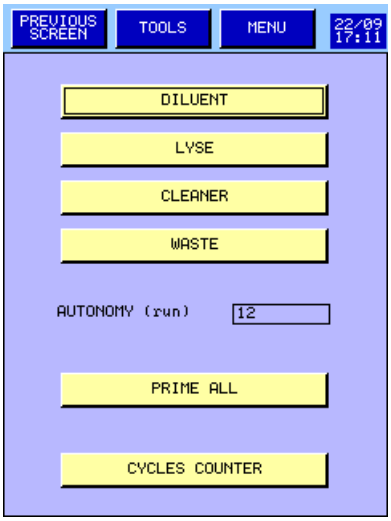
- The main menu is displayed.
- Press on REAGENTS.



- If this window appears, it means that several results in memory have not been sent before the MYTHIC 18 was switched off.
- Press YES to send them immediately, or press LATER to wait at another time or NO if you do not want to send them.


WARNING
SOME RESULTS HAVE BEEN NOT SAVED ONTO THE EXTERNAL STORAGE DEVICE. DO YOU WANT THESE FILES TO BE MOVED ONTO IT ?
NO
LATER
YES

- No USB key is available, connect an USB key then press YES or see section 3.4.7 to change the archive mode.

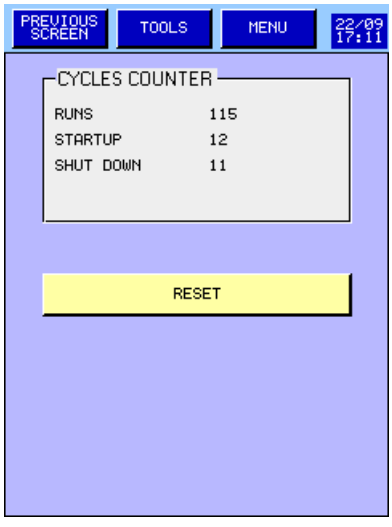


- Press PRIME ALL : The **MYTHIC 18** performs a complete priming cycle.

- The cycle LED turns red. No cycle can be performed before it turns green.

- **AUTONOMY (run)** indicates the number of samples (runs).
- To prime or to know the quantity of reagent press the dedicated button.

- Press CYCLES COUNTER to visualize the cycle counters.



- The reset of the counter is allowed by an Orphée's representative only.

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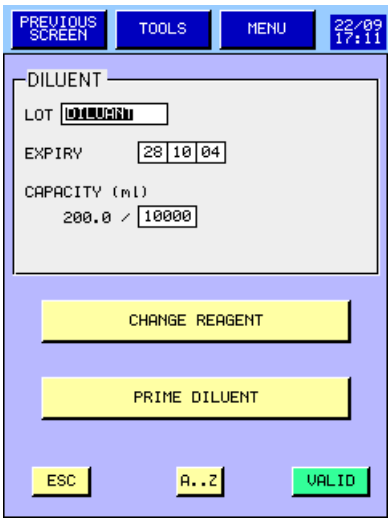
DILUENT PRIME:



- From the **MAIN MENU** press REAGENTS then DILUENT to have access to this screen.

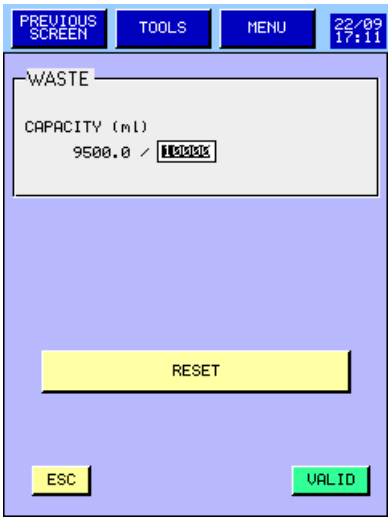
- Enter lot number, the expiry date and the container capacity.

- Press CHANGE REAGENT to validate the new entry or after changing a new container with the same information.

- After the replacement a new container or to prime the diluent, press PRIME DILUENT

- A new entry is automatically done in the logs (see section 5.9)

LYSE AND CLEANER PRIME:
Proceed as described above for the diluent.



WASTE:

- Enter only the capacity of the container.

- After replacement of the waste container press RESET to reset to initialize the waste calculation.

MYTHIC 18 IS NOW READY TO WORK.

1.6 TRANSPORTATION AND STORAGE

Storage temperature: -10°C to +50°C.
Before transportation outside the laboratory, perform a complete cleaning with a disinfectant in compliance with the local legislation.

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2. GENERAL OVERVIEW

2.1 GENERALITIES

MYTHIC 18 is a fully automated analyzer performing hematological analysis on whole blood collected on EDTA tubes.

- Sample volume : 9,8 µl
- Throughput : 60 samples/hour
- 18 analysis parameters :

Leukocyte parameters:

WBC	White Blood Cells
LYM%	Lymphocytes in percentage
LYM#	Lymphocytes
MON%	Monocytes in percentage
MON#	Monocytes
GRA%	Granulocytes in percentage
GRA#	Granulocytes

Erythrocyte parameters

RBC	Red Blood Cells
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Blood cells Distribution Width

Thrombocyte parameters

PLT	Platelet
MPV	Mean Platelet Volume
PDW*	Platelet Distribution Width
PCT*	Thrombocrit

* For Investigation Use only in the United States of America.

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2.2 OVERVIEW

MYTHIC 18 consist of 8 main parts:

1. Display / Keyboard.
2. Dilution hydraulic part.
3. Mono electronic board.
4. Reagent tray.
5. Connection.
6. External power supply block.
7. Printer.
8. Barcode reader (option).

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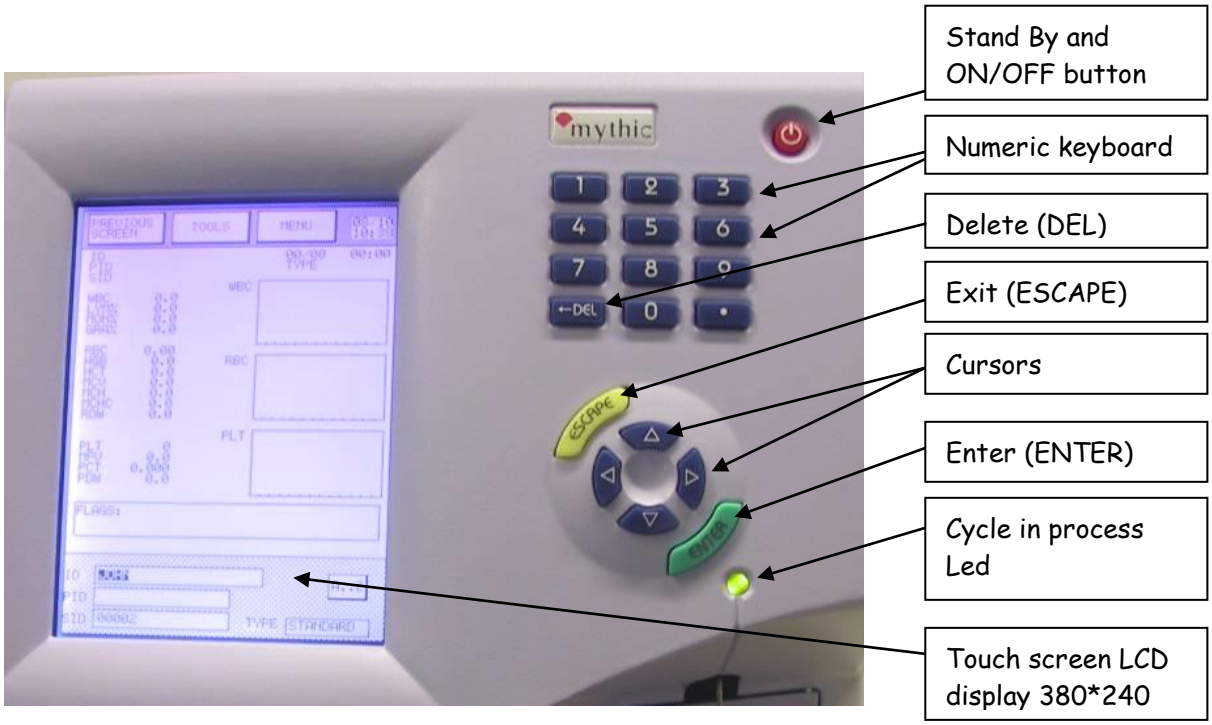
2.3 MAIN PART DESCRIPTION

2.3.1 Display / Keyboard



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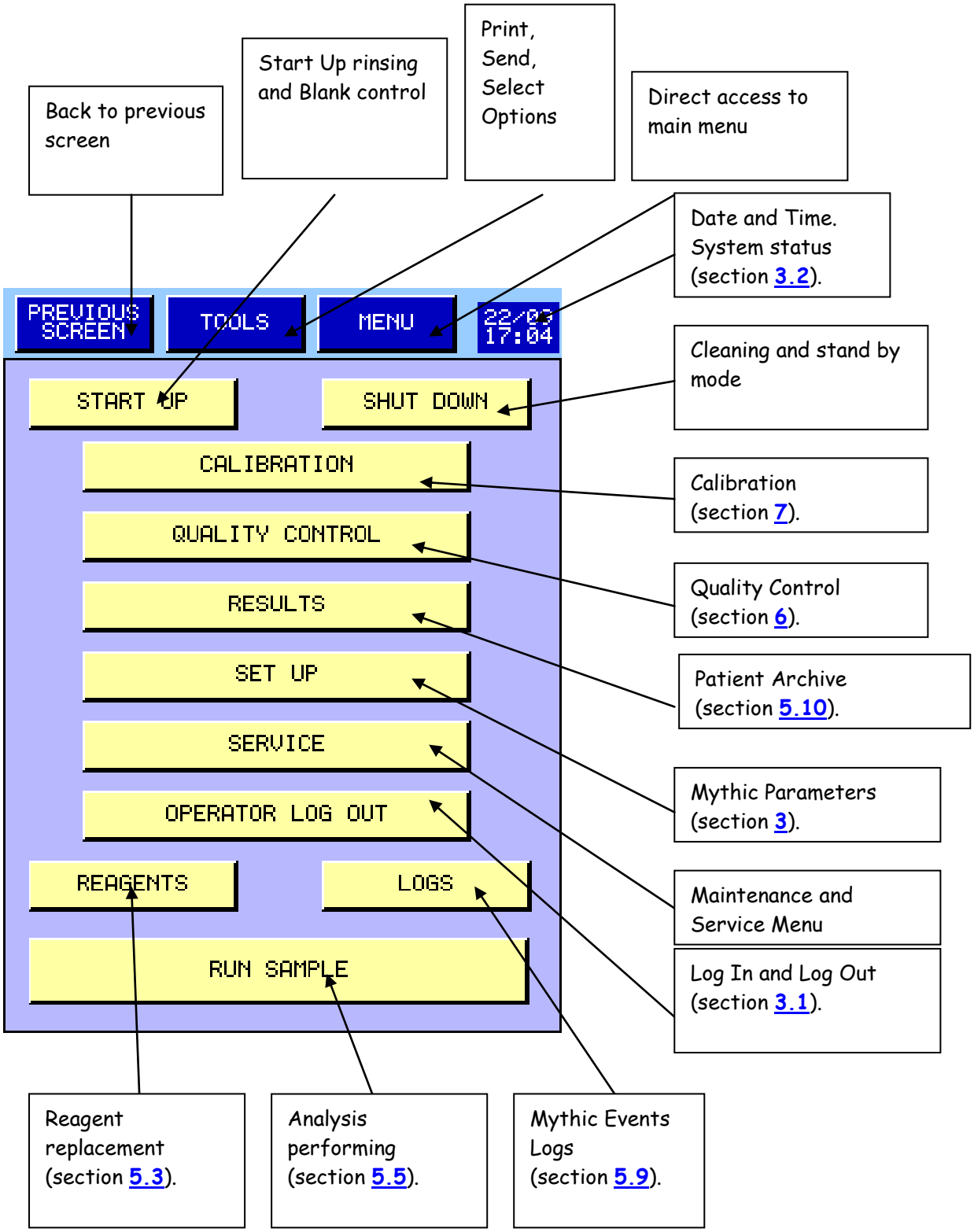
Main Menu description



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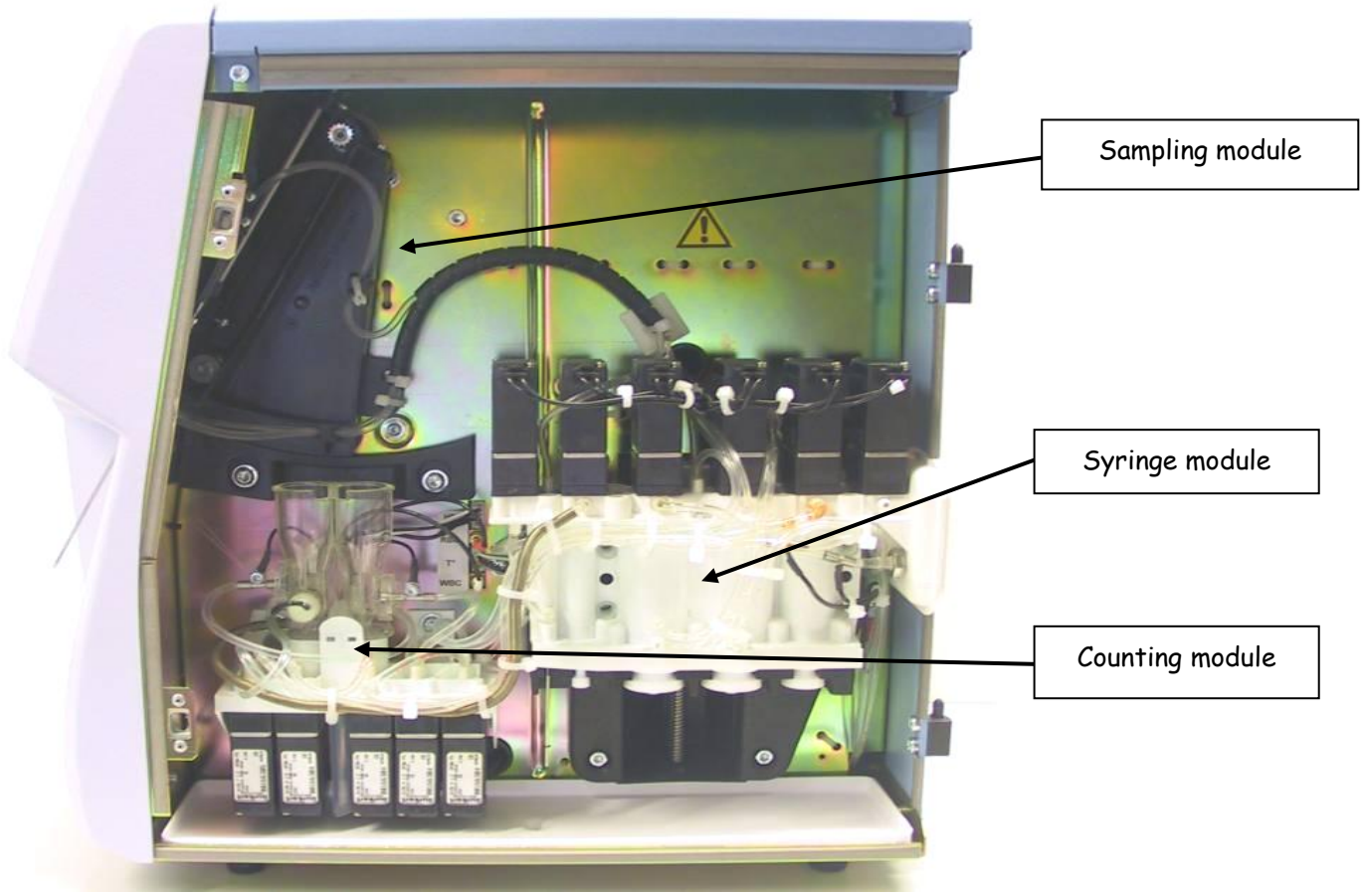
2.3.2 Dilution hydraulic part

All the fluidic part is on the right side of the instrument and consists of only three modules:

- Sampling module :
  - Rocker (patent pending): Manages the rise and descent of the needle.
- Syringe module (patent pending) consists of one block :
  - Reagent syringes (Diluent, lysis), sampling and air syringes.
  - Liquid valve manifold assembly and tubing.
- Counting chambers :
  - WBC and RBC counting chambers and hemoglobin measurement.
  - Liquid valve manifold assembly and tubing.



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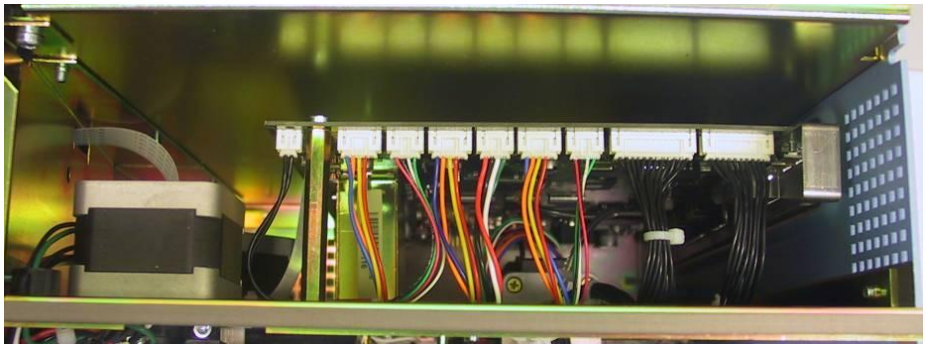
2.3.3 Mono electronic board



The mono electronic board is located between the hydraulic part and the reagent tray.
The board, driven by a 32-bit processor, manages the following parts:

- Sample needle, rocker, syringe block motors.
- Display and keyboard.
- Connexion mode (RS232, Ethernet, …).
- Printer.
- Measurement (Counting, hemoglobin measurement).
- Data processing.
- External barcode reader.

	To avoid all deterioration risks, only the service people can touch this electronic board.

2.3.4 Power Supply Block

MYTHIC 18 is supplied with an external power supply block.

	- In the case of replacement of the main power wire supplied with the MYTHIC 18 the new one must comply with the local regulation. **- The MYTHIC 18 has been certified with the power supply box provided with the machine. The use of another external power supply box is not guaranteed. Please contact your Orphée's representative.**

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2.3.5 Reagent tray

The reagent tray is dedicated for the lysis and cleaning solution bottles.

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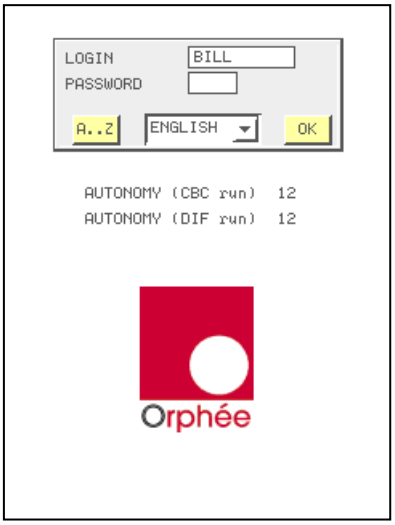
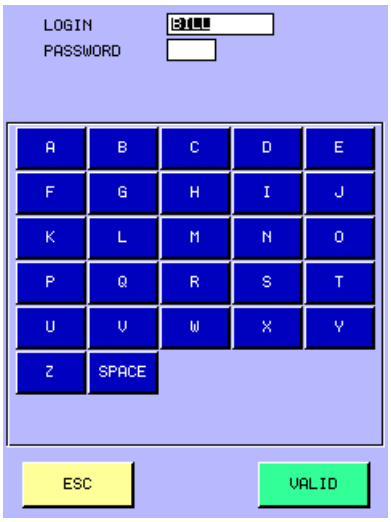
3. INSTRUMENT SET UP

3.1 USER'S IDENTIFICATION

3.1.1 Start Up

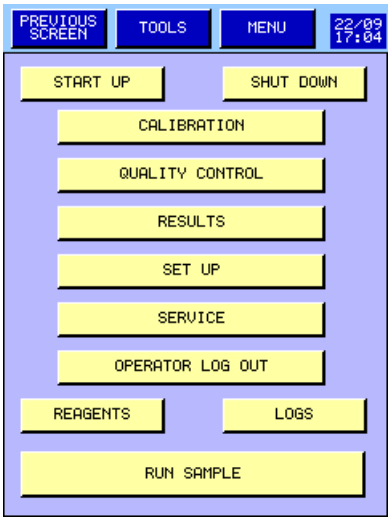


- After the instrument's initialization, the identification window is displayed.
- In the window LOGIN BILL, the last operator's identification appears.
- Either the identification is yours, press PASSWORD and enter your password or the identification is not, press A..Z to enter your login.
- The window ENGLISH enables to change the language. Press OK to validate it.
- **AUTONOMY (run)** indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).



- Enter your identification name with the alphabetic keyboard.
- Place the cursor in the Password window.
- Enter your password for identification.
- For the first login, **MYTHIC 18** propose 3 access levels:
  - **User :** No password
  - **Biologist** : Password by default **1- 2- 3**
  - **Service people**
- Biologist Password can be modified in section 3.4.6.

3.1.2 In process



- To change operator during the process, press MENU to return to the main menu, and then press on OPERATOR LOG OUT

- To change identification, proceed as described above (section 3.1.1).

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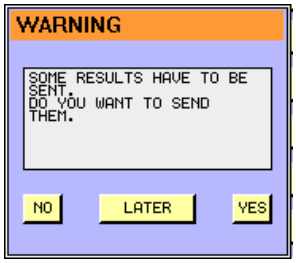
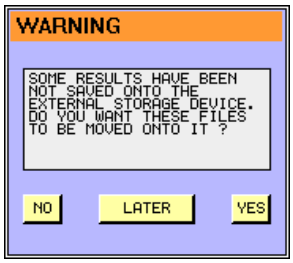
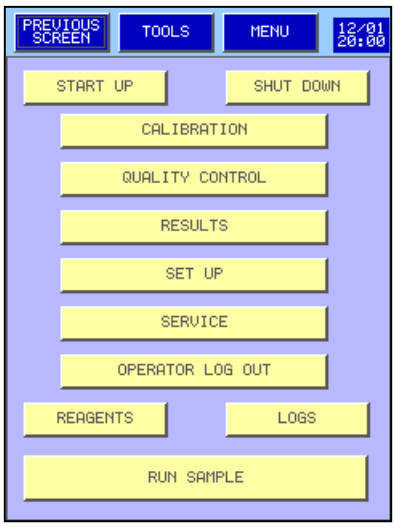


- If this window appears, it means that several results in memory have not been sent before the MYTHIC 18 was switched off.
- Press YES to send them immediately, or press LATER to wait for another time, or NO if you do not want to send them.


WARNING
SOME RESULTS HAVE BEEN NOT SAVED ONTO THE EXTERNAL STORAGE DEVICE.
DO YOU WANT THESE FILES TO BE MOVED ONTO IT ?
NO
LATER
YES

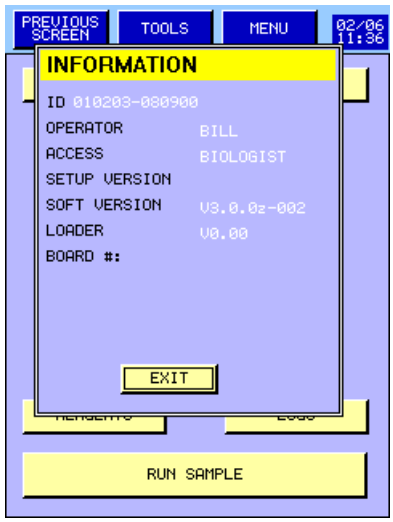
- No USB key is available, connect an USB key then press YES or see section 3.4.7 to change the archive mode.

3.2 SYSTEM STATUS



- Press on the date and hour

to have access to the system status window.



- Different system status information is displayed.

- To return to the **MAIN MENU** press

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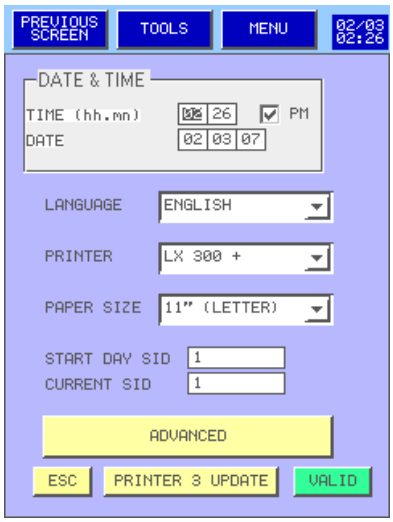
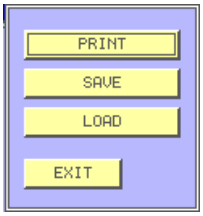
3.3 SET UP



- From the **MAIN MENU** press on SET UP
- This menu is available for all users.
- The **DATE & TIME** window enables to modify the time and the date
- To select the language of the Mythic menu, choose the right one in the Language combo box. LANGUAGE ENGLISH
- PRINTER LX 300 + : Select the printer or no printing.
- PAPER SIZE 11" (LETTER) : Select the paper size depending on the number of results per page.
- START DAY SID 1 : Two SID are available; Start day SID enables to select the first SID for each new day.
- CURRENT SID 1 : If you want to select a new SID number
- ADVANCED : Biologist reserved for complete settings.

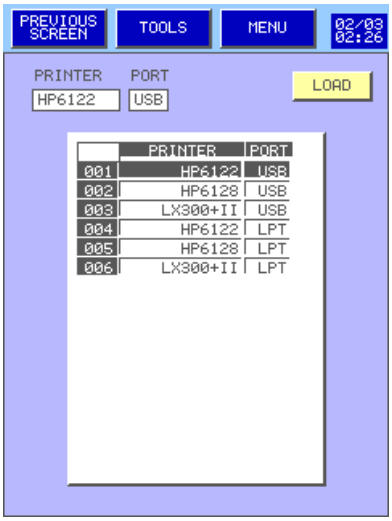
(See section 3.4).

- Once modifications are done, press either VALID to valid or ESC to exit keeping the previous setting.

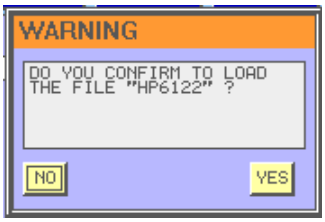


- Press TOOLS to print, save or load from an USB key all the set up.

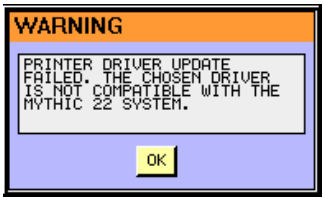
- To load new printer drivers plug the USB key then press on PRINTER 3 UPDATE in the previous screen.



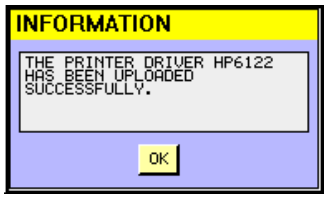
- Select the printer and its connection mode.
- Then press LOAD



- Press YES then, the driver is loaded in the MYTHIC 22



- This prompt appears if the release is failed. Check the USB connection or change the USB key or call your Orphée's representative.



This prompt appears if the release is done successfully.

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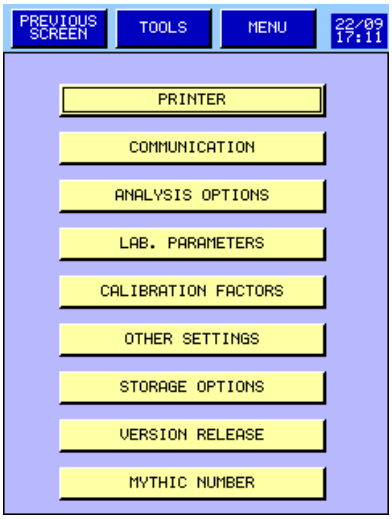
3.4 ADVANCED SET-UP

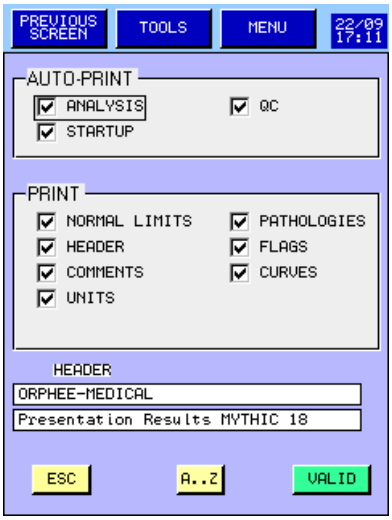


- **This menu is reserved to biologist** (see section 3.1).

	Any modifications can affect the quality of the results. We recommend modifying these values only after an Orphée's training.

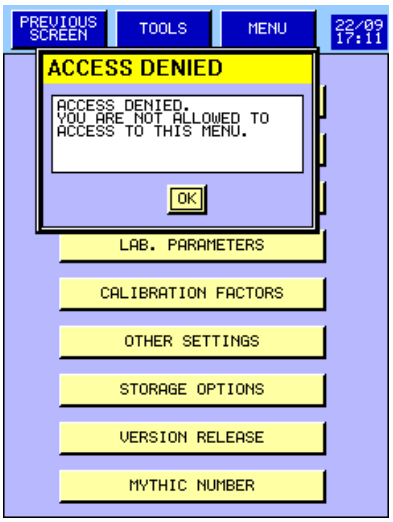
- Please refer below for the description of each key.

3.4.1 Printer set up:



- Printer set up menu is intended to present the printing report
- To select an option on the report, press on the corresponding case.
- To enter a header, press A..Z key.
- To exit the menu, either press ESC to keep the last setting, or VALID to save the last modifications.

3.4.2 Communication:



- Reserved for technical Service people.
- To set up the connection between **MYTHIC** and Host or between **MYTHIC** and **SVM** (Validation **S**tation for **MYTHIC**).

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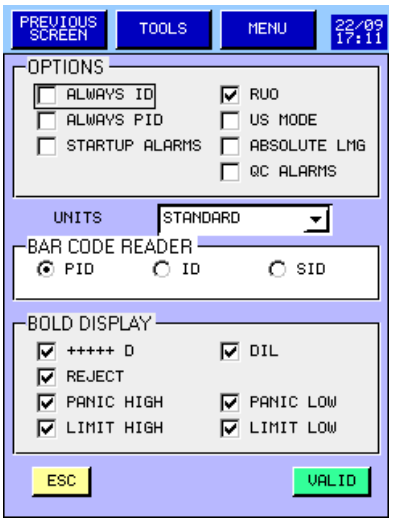
3.4.3 Analysis options:

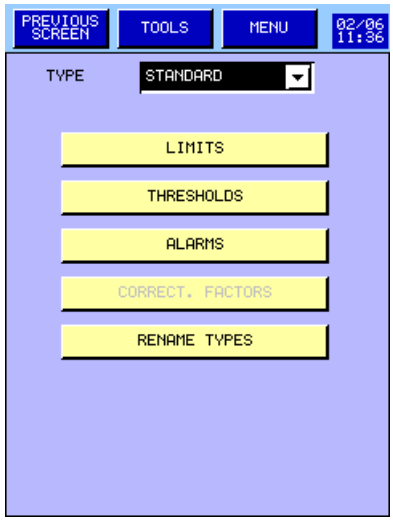


- **OPTIONS** box:
  - **ALWAYS ID** and **ALWAYS PID**: To run a sample, user mandatory needs to enter a ID and/or a PID.
  - **RUO**: With tag the PCT and PDW parameters are displayed, printed and sent.
  - **US MODE**: The Research Use Only message is printing below the printing report (only if RUO is tagged).
  - **ABSOLUTE LMG**: With tag absolute values for sub-populations of leucocytes are displayed. In the other case, percentages are displayed.
  - **QC ALARMS**: The message "QC failed" appear below the printing report when the QC result is out of tolerance or expired; The message "QC not done" appear below the printing report when it is not run.

- UNITS STANDARD : Gives a choice of three unit systems : Standard, International System, and mmol.
- **CDB** box: The bar code reader is dedicated to the PID, ID or SID.
- **BOLD DISPLAY** box: display and print in bold-faced type the different choices in this box.

Once modifications are done, press either VALID to validate your choices or ESC to exit keeping the previous setting.

3.4.4 Lab. parameters:



- Select the blood type in the combo box TYPE STANDARD then press:

LIMITS to adjust the normal and panic limits (see section **3.4.4.1**).

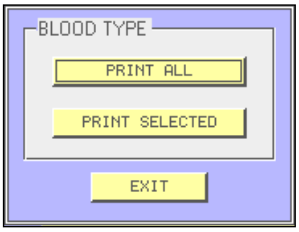
THRESHOLDS to adjust the parameters thresholds (see section **3.4.4.2**).

FLAGS LEVEL to adjust the flags level (see section **3.4.4.3**).

CORRECT. FACTORS to adjust the corrections factors (see section **3.4.4.4**).**NOTA**: No correction factors with type STANDARD.

- To enter a new blood type, press RENAME TYPES

NOTA: The name of the first type STANDARD cannot be change.



- Press TOOLS to print the blood type set up.
- PRINT ALL allow to print all the blood type set up (about **20** pages are printed)
- PRINT SELECTED only the blood type in the combo box is printed.

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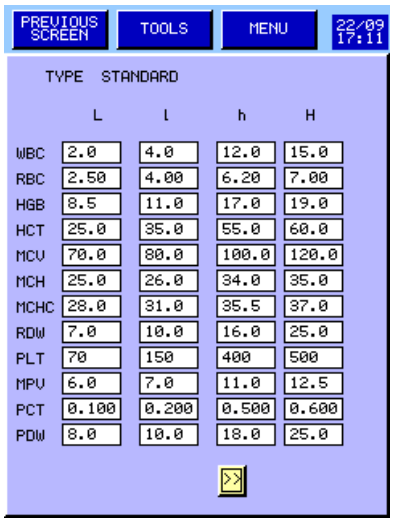
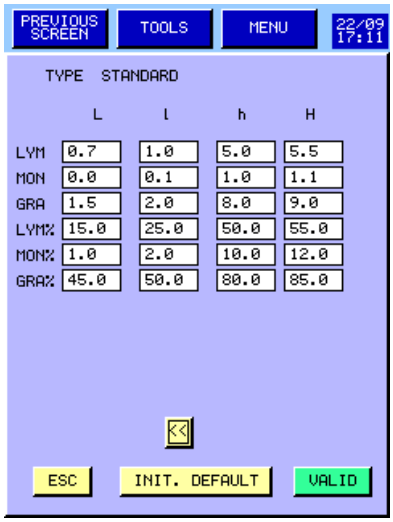
3.4.4.1 Limits:



- This display enables to enter normal and panic limits for every 18 parameters given by the **MYTHIC 18** (see section 8).

- To validate the new values, press VALID key in the next page (see below).



- Once modifications are done, press VALID to validate or ESC to exit without any modification.

- Press INIT. DEF. to return to the manufacturer parameter setting.

Example of reference values from **LABORATOIRE D'HEMATOLOGIE DU C.H.U. D'ANGERS (FRANCE)**

	First week	8 days to 3 months	3 months to 3 years	3 to 6 years	6 to 15 years	Adult
WBC $10^3/\mu L$ ($10^9/L$)	10,0 to 30,0	6,0 to 18,0	6,0 to 15,0	5,0 to 13,0	5,0 to 11,0	4,0 to 10,0
Neutrophiles ($10^3/\mu L$)	6,0 to 26,0	1,5 to 8,5	1,5 to 8,5	1,5 to 8,5	1,8 to 8,0	1,8 to 7,5
Eosinophiles ($10^3/\mu L$)	0,2 to 0,85	0,2 to 1,2	0,05 to 0,7	0,02 to 0,65	0 to 0,6	0,04 to 0,8
Basophiles ($10^3/\mu L$)	0 to 0,64	0 to 0,2	0 to 0,2	0 to 0,2	0 to 0,2	0 to 0,2
Lymphocytes ($10^3/\mu L$)	2,0 to 11,0	2,0 to 11,0	4,0 to 10,5	2,0 to 8,0	1,5 to 6,5	1,0 to 4,5
Monocytes ($10^3/\mu L$)	0,4 to 3,1	0,05 to 1,1	0 to 0,8	0 to 0,8	0 to 0,8	0,2 to 1,0
RBC $10^6/\mu L$ ($10^{12}/L$)	5,0 to 6,0	3,8 to 4,8	3,6 to 5,2	4,1 to 5,3	4,0 to 5,4	M : 4,5 to 5,8 F : 3,8 to 5,4
HGB g/dL	14,5 to 22,5	10 to 16	10,5 to 13,5	10,5 to 13,5	11,5 to 14,5	H : 13,5 to 17,5 F : 12,5 to 15,5
HCT %	44 to 58	38 to 44	36 to 44	36 to 44	37 to 45	M : 40 to 50 F : 37 to 47
MCV fl	100 to 120	85 to 96	70 to 86	73 to 89	77 to 91	82 to 98
MCH pg	34 to 38	24 to 34	23 to 31	24 to 30	24 to 30	> or = 27
MCHC g/dL	32 to 36	32 to 36	32 to 36	32 to 36	32 to 36	32 to 36
PLT $10^3/\mu L$ ($10^9/L$)	150 to 400	150 to 400	150 to 400	150 to 400	150 to 400	150 to 400

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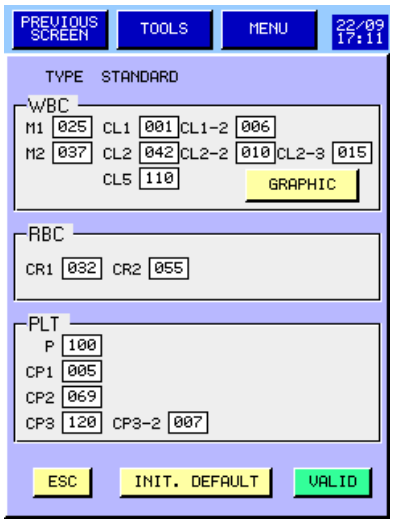
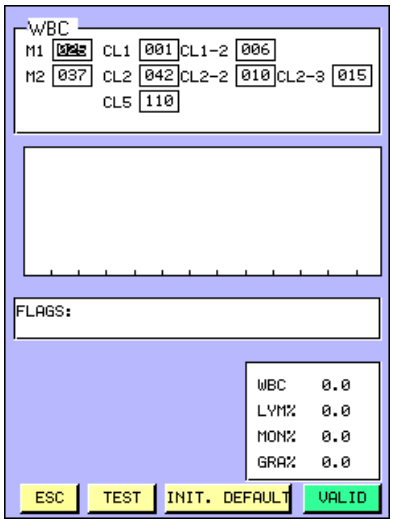
3.4.4.2 Thresholds:



- The threshold display enables to modify the detection thresholds located on the WBC, RBC, PLT curves.

	Threshold modifications can affect the quality of the results or can affect the alarm detection area. We recommend modifying these values only after an Orphée's training.

- Once modifications are done, press VALID to validate or ESC to exit without any modification.
- Press INIT. DEF. to return to the manufacturer parameter setting.



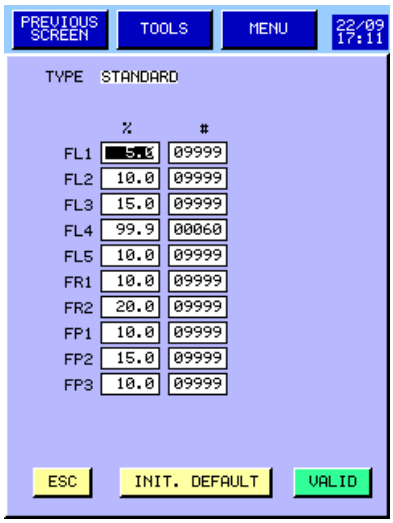
- This screen allows displaying the WBC thresholds position after a run.

- After modification press TEST to allow the recalculation and check the results and flags.

- Once modifications are done, press VALID to validate or ESC to exit without any modification.

- Press INIT. DEF. to return to the manufacturer parameter setting.

3.4.4.3 Alarms:



- In the Alarm menu, users can modify the sensitivity of the alarms for the different cells (WBC, RBC and PLT).

- Once modifications are done, press VALID to validate or ESC to exit without any modification.

- Press INIT. DEF. to return to the manufacturer parameter setting.

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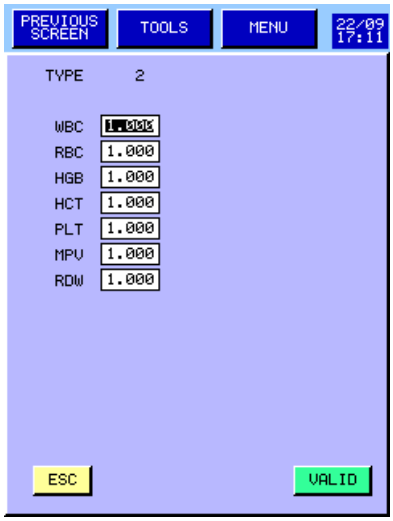
3.4.4.5 Correction factors:

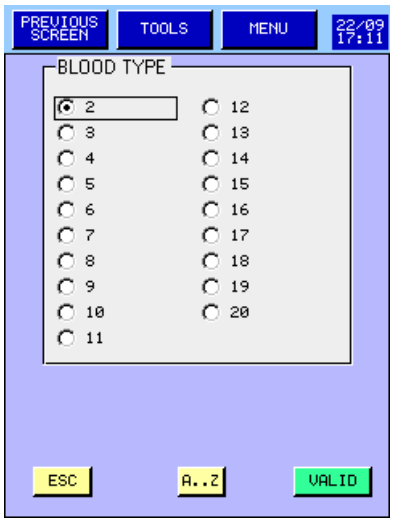


- This function can be reached only for any other type than the standard.

- In this menu, for each blood type, users can define a correction factor which is multiplied by the calibration factor given by a normal calibration (see section 7).

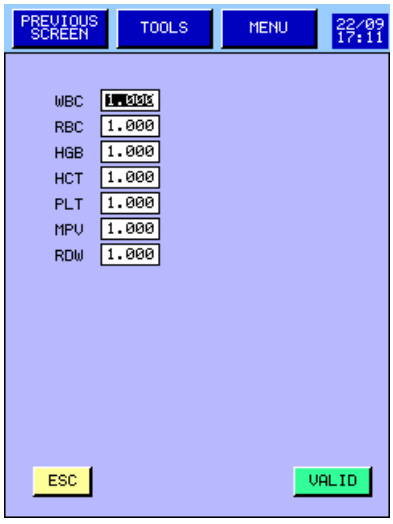
- Once modifications are done, press VALID to validate or ESC to exit without any modification.

3.4.4.4 Rename Types:



- In the Blood type menu, users can define the limits, thresholds, alarms and calibration correction factors associated to each blood type.
- To modify the name of the blood type:
  - Select the type
  - Press A..Z
  - Input the new name.
  - Press VALID to validate or ESC to exit without any modification.

3.4.5 Calibration factor:



- In this menu, the user can modify the calibration factors without any calibration with calibration blood.

	The modification of any of these factors without running a calibration blood could affect the quality of the result.

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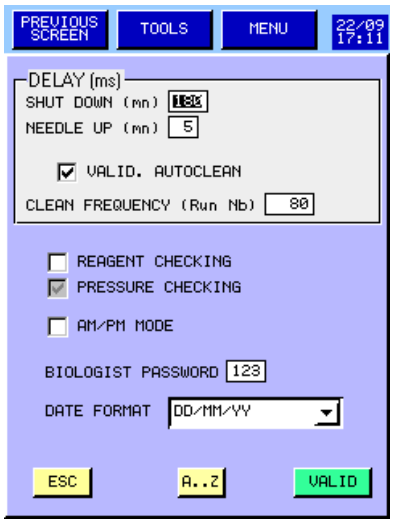
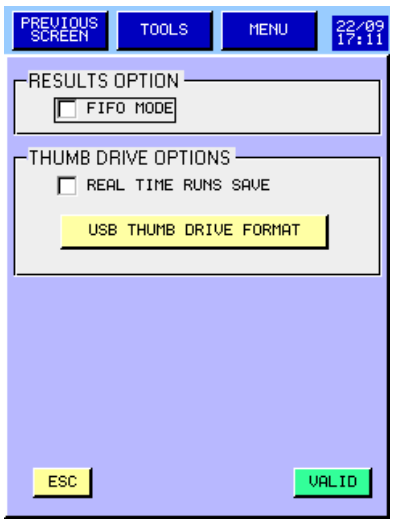
3.4.6 Other Setting:



- In **DELAY** box, the user can modify:
  - Time in minutes to start the automatic shut down.
  - Time in minutes to build up the needle.
  - The setting up of the automatic cleaning and its frequency in number of analysis.
- Reagent checking enables the reagent control (see section 1.5.2)
- Pressure checking enables the pressure control during a measurement cycle (see section 9.6).
- AM/PM mode enables to display the time of your choice.
- BIOLOGIST PASSWORD 123 enables to modify the biologist password.
- DATE FORMAT DD/MM/YY enables to select the date format.
- Once modifications are done, press VALID to validate or ESC to exit without any modification.

3.4.7 Storage options:

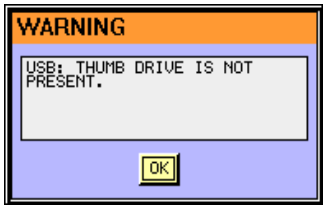


- Choose for a FIFO (first in /first out) mode or real time to store the results in the resident memory or in a USB key.

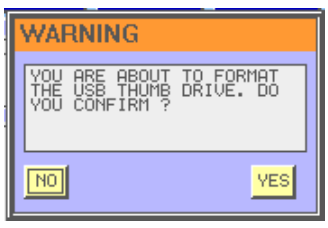
- REAL TIME RUNS SAVE enables to save the results in the USB key at the end of each measurement cycle.

- Press VALID to save the modification.

Press USB THUMB DRIVE FORMAT to format USB key. The system will format the USB Key and build specific directories for Mythic management.



- This prompt appears if none USB key is available.



- Press yes if you agree to format the USB key. It is mandatory to format the USB key on the Mythic before to use it.

	All the information includes in the USB key will be erased.

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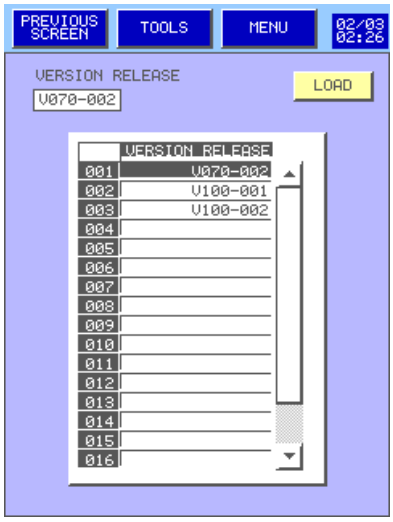
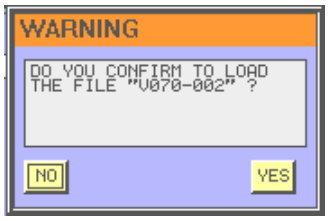
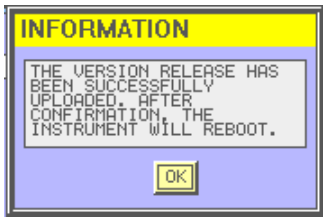
3.4.8 Version release:



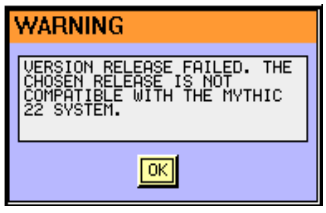
- Press LOAD to load a new software version from a USB key.
- Choose the right version then,
- Press yes only if you are sure to load new version software.



	The current software version will be erased definitively.



- This prompt appears to confirm the version loading.



- This prompt appears when the release of the software is failed.

- Choose another version or call your Orphée's representative.

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4. SPECIFICATIONS

4.1 ANALYTICAL SPECIFICATIONS

Throughput: 60 samples/hour (approx.)

Sample Volume: 9,8 µl (approx.)

Measurement Principle: WBC/RBC/PLT: Impedancemetry
Hemoglobin: Spectrophotometry at 555 nm
Hematocrit: Volume integration

Linearity:
Linearity is measured with linearity sample performed four times for each level.

PARAMETERS	RANGE	LIMITS (the larger)
WBC (10^3/mm^3)	0 to 100	+/- 0,4 or +/- 4%
RBC (10^6/mm^3)	0,1 to 8	+/- 0,07 or +/- 3%
HGB (g/dL)	0,5 to 24	+/- 0,3 or +/- 2%
HCT (%)	5 to 70	+/- 2 or +/- 3%
PLT (10^3/mm^3)	5 to 2 000	+/- 5 or +/- 5%

Reportable range:
Within the reportable range, the results are flagged with a **D** to indicate that it is necessary to re-dilute and re-run the sample.

PARAMETERS	REPORTABLE RANGE
WBC (10^3/mm^3)	100 to 150
RBC (10^6/mm^3)	8 to 15
HCT (%)	70 to 80
PLT (10^3/mm^3)	2000 to 4 000

Repeatability:
Calculated with 20 runs of a fresh whole blood sample performed on a commercial **MYTHIC 18**.

PARAMETERS	CV	RANGE
WBC	< 2,5%	> to 6,0×10^3/mm^3
LYM	< 5%	> to 15 %
MON	< 10%	> to 5 %
GRA	< 3%	> to 50 %
RBC	< 2%	> to 4,0×10^6/mm^3
HGB	< 1,5%	> to 12,0 g/dL
HCT	< 2%	> to 35,0 %
MCV	< 1%	> to 85 fL
RDW	< 3%	> to 12
PLT	< 5%	> to 200×10^3/mm^3
PMV	< 3%	> to 7 fL

Calculated method: $CV = \frac{SD}{\bar{X}}$

$$SD = \sqrt{\frac{\Sigma x^2 - \frac{(\Sigma x)^2}{N}}{N - 1}}$$

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Carry-Over:
For each parameter, we perform 3 runs from high concentration sample followed by 3 runs from empty cycles.

	WBC	RBC	HGB	PLT
High concentration value	18,0	5,33	17,9	466
Measured carry-over (%)	0	0,18	0	0,6
Maximum carry-over (%)	< 1,0	< 1,0	< 1,0	< 1,0

The percentage of carry-over inter samples is calculated with the following formula :

$$\text{Carry-over} = \frac{\text{(Result empty cycle 1) - (Result empty cycle 3)}}{\text{(Sample 3) - (Result empty cycle 3)}} \times 100$$

Accuracy:
Correlation with one commercial instrument (ABX PENTRA 120) and with 100 normal blood samples (without alarm) for all the parameters except LMG.
Correlation with one commercial instrument (ABX MICROS 60) and with 31 normal blood samples for LMG.

PARAMETERS	N	R (%)
WBC (10^3/mm^3)	97	0,9985
LYM (%)	31	0,9801
MON (%)	31	0,9533
GRA (%)	31	0,9860
RBC (10^6/mm^3)	99	0,9958
HGB (g/dL)	99	0,9973
HCT (%)	99	0,9898
MCV (fL)	99	0,9783
RDW (%)	99	0,6000
MCH (pg)	99	0,9789
MCHC (g/dL)	99	0,4020
PLT (10^3/mm^3)	99	0,9940
MPV (fL)	99	0,9196

Calculated method: $$\mathbf{r} = \frac{n.\Sigma xy - \Sigma x.\ \Sigma y}{\sqrt{(n.\ \Sigma x^2 - (\Sigma x^2))(n.\ \Sigma y^2 - (\Sigma y^2))}}$$

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4.2 PHYSICAL SPECIFICATIONS

General:
Ambient temperature: from 18 to 32°C
Relative Humidity: 80% maximum at 32°C
Storage temperature: -10 to 50°C

If the MYTHIC 18 has been stored at a temperature less than 10°C, it must stay at room temperature during 24 hours before switching it on.

INSTRUMENT:

Dimensions: Height: 350 mm (approx.)
Width: 250 mm (approx.)
Depth: 340 mm (approx.)

Weight: 9kg (approx.)

Power supply Input: 24V – 3A DC

Electric consumption: In cycle: 30 VA (-30% +10%)
Stand By: 20 VA (-30% +10%)
Maximum: 50 VA (-30% +10%)

Display: Monochrome LCD 240*320
Mode portrait
Retro-lighted

Barcode (option): Barcode reader: C39/ Barcode / 2 interleaved 5

Memory capacity: > 1000 Files (Demographics, results and histograms)
QC: 6 levels (100 Files per level)

Connection: RS 232C
Ethernet (TCP/IP)

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Reagent Consumption (ml): Software Version **0.5.x**

CYCLES		DILUENT	LYSE	CLEANER
Run Sample		12,80	0,34 **	0,42
Rinse All		6,00	--	--
Back flush		6,00	--	0,20
Control		10,00	--	0,84
Reagent Prime	**All**	28,00	4,00	9,00
	Lyse	12,00	3,00	--
	Diluent	30,00	--	--
	Cleaner	--	--	8,60
Cleaning		6,00	--	2,10
Bleach		6,00	--	--
Start Up *		32,80	0,34**	0,42
Shut Down		--	--	15,00

***** Consumption with one run sample, add one or two run sample consumption if needed.

****** The consumption of the lysis is given for the ORPHEE reagent with a standard adjustment. To change the quantity to use another lysis, please contact your ORPHEE representative.

POWER SUPPLY BLOCK:

Dimensions: Height: 31 mm (approx.)
Width: 58,5 mm (approx.)
Depth: 132 mm (approx.)

Weight: 0,35 kg (approx.)

Power supply Input: 100 to 240V AC - 1,5A
50-60Hz

PRINTER (LX-300+):

Dimensions: Height: 164 mm (approx.)
Width: 366 mm (approx.)
Depth: 275 mm (approx.)

Weight: 4,4 kg (approx.)

Power supply: Model 120V Model 220-240V
99 to 132Vac 198 to 264Vac
50 to 60 Hz

Electric consumption: 23W (approx.)

Paper size: A4

Printer: Impact (9 needles)

Speed: Up to 300 cps (character per second)

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4.3 REAGENTS SPECIFICATIONS

All the reagents must be stored at room temperature (15°C to 25°C).

4.3.1 Diluent

ORPHEE code number: **HM18-003-10**
Shelf life once opened: 60 days.

Application: The diluent is used to carry out the necessary dilutions for the measurement performed by the **MYTHIC 18**.(see section **8**)

Active components: 0,45% Sodium Chloride.
1,00% Sodium Sulfate.

Others components: Buffer.
Preservative.

Description: Clear and odorless aqueous solution.

Storage: At room temperature until the expiry date labeled on the bottle.

Precautions: Can cause skin and eyes irritation. Wear a smock, gloves and glasses during manipulation.

First emergency care:
Inhalation: Breathe fresh air.
Eyes: Abundantly rinse during 15 mn.
Skin: Abundantly rinse.
Ingestion: Vomit.

If any doubt, call an emergency center.

4.3.2 Lysis reagent

ORPHEE code number: **HM18-002-1**
Shelf life once opened: 60 days.

Application: Lytic reagent is used to lyse the red blood cells, the leukocyte differentiation and the cyanmethemoglobin complex formation used during the measurement performed on the **MYTHIC 18** (see section **8**)

Active components : 3,50% surfactant.
0,03% Potassium cyanide.
Quaternary ammonium salt.

Description : Clear aqueous solution with a light almond odor.

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Storage: At room temperature, until expiry date labeled on the bottle.

Precautions: Can cause skin and eyes irritation. Wear a smock, gloves and glasses during manipulation.

First emergency care:
Inhalation: Breathe fresh air.
Eyes: Abundantly rinse during 15 mn.
Skin: Abundantly rinse.
Ingestion: Vomit.
If any doubt, call an emergency center.

4.3.3 Cleaning solution

ORPHEE code number: **HM18-001-1**
Shelf life once opened: 60 days.

Application: The cleaning solution is used to carry out the cleaning of the measurement system and hydraulic circuit (see section **8**).

Components: Enzyme
Potassium and Sodium salts.
Surfactant and preservatives.
Coloring agent.

Description: Clear aqueous solution, blue color.

Storage: At room temperature, until expiry date labeled on the bottle.

Precautions: Can cause skin and eyes irritation. Wear on a smock, gloves and glasses during manipulation.

First emergency care:
Inhalation: Breathe fresh air.
Eyes: To rinse abundantly during 15 mn.
Skin: To rinse abundantly.
Ingestion: Vomit.
If any doubt, call an emergency center.

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4.4 ANALYTICAL LIMITATIONS

4.3.1 Recommendations

MAINTENANCE:
Please respect the maintenance procedure and the quality control procedure. Otherwise, results can be affected.

GENERALITIES:
Some abnormal samples may give incorrect results by automated cell counting methods. The following table shows examples of specific specimens that could cause errors.

Each result for a new patient out of lab linearity limits or with an alarm must be checked with a conventional method or checked with blood smear.

4.3.1 Interferences

Parameter	**Specimen**		**Possible Indication of Error**
WBC	Cold Agglutinin	(+)	↑MCV, ↓HCT, red cell clumping on smear
	Nucleated RBC	(+)	NRBC on smear
	Cryoglobulins	(+)	
	Platelet aggregation	(+)	Platelet aggregates on smear
	Erythroblastosis	(+)	Erythroblasts on smear
RBC	Cold Agglutinin	(-)	↑MCV, ↓HCT, red cell clumping on smear
	Severe Microcytosis	(-)	
	Fragmented RBC	(-)	
	Leukocytosis (>100,000/µL)	(+)	Elevation of WBC
HGB	Leukocytosis(>100,000/µL)	(+)	Elevation of WBC
	Lipemia	(+)	↑MCHC, "milky" appearance of plasma
	Abnormal Protein	(+)	↑MCHC, Lysed Hgb/WBC sample turns cloudy
HCT	Cold Agglutinin	(-)	↑MCV, ↓HCT, red cell clumping on smear
	Leukocytosis(>100,000/µL)	(+)	Elevation of WBC
	Abnormal Red Cell Fragility	(?)	
	Spherocytosis	(?)	↓MCV, spherocytes on smear
PLT	Pseudothrombocytopenia	(-)	Platelet Satellitism on smear
	Platelet Aggregation	(-)	Platelet Aggregates on smear
	Increased Microcytosis	(+)	↓MCV
	Megalocytic Platelets	(-)	

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

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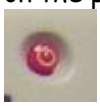
5. SAMPLE ANALYSIS

5.1 VERIFICATIONS BEFORE STARTING

Before starting **MYTHIC 18**, we recommend to check the reagent levels in each bottle, and the level of the waste container. Please also check the paper quantity in the printer.

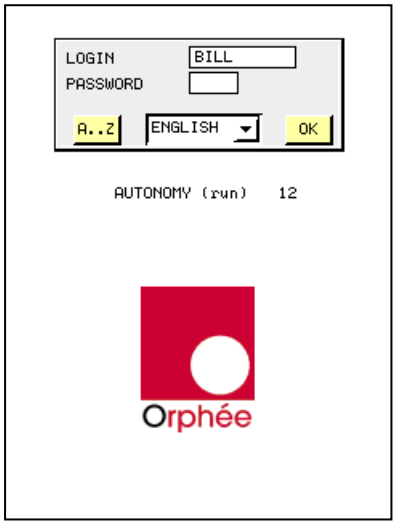
5.2 START UP

- Press ON/OFF button on the printer to start.

- Press ON/OFF button  on the Mythic.

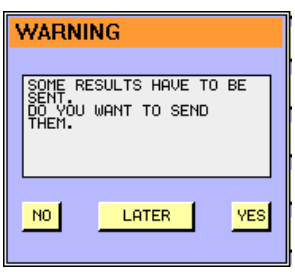
- The initialization menu is displayed and **MYTHIC 18** performs a home position checking for the three motors.

- The cycle LED turns red. None cycle can be performed before it turns green.



- Enter your login and password as described in section 3.1.

- **AUTONOMY (run)** indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).



- If this window appears, it means that several results in memory have not been sent before the MYTHIC 18 was switched off.
- Press YES to send them immediately, or press LATER to wait at another time or NO if you do not want to send them.

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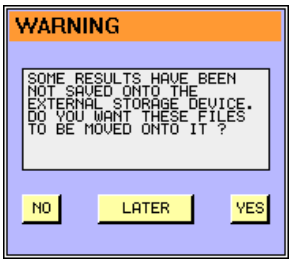
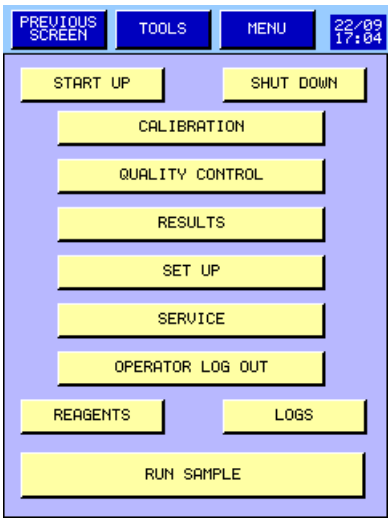
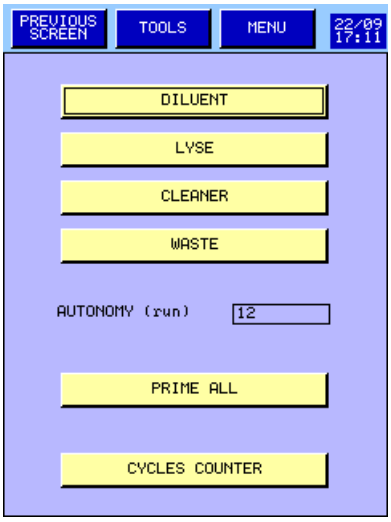

WARNING
SOME RESULTS HAVE BEEN NOT SAVED ONTO THE EXTERNAL STORAGE DEVICE. DO YOU WANT THESE FILES TO BE MOVED ONTO IT ?
NO
LATER
YES

- No USB key is available, connect an USB key then press YES or see section 3.4.7 to change the archive mode.

5.3 REAGENT REPLACEMENT



- To check the level of each reagent, press



- If one or more reagent needs to be replaced, proceed as indicated in section 1.5.2

- **AUTONOMY (run)** indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).

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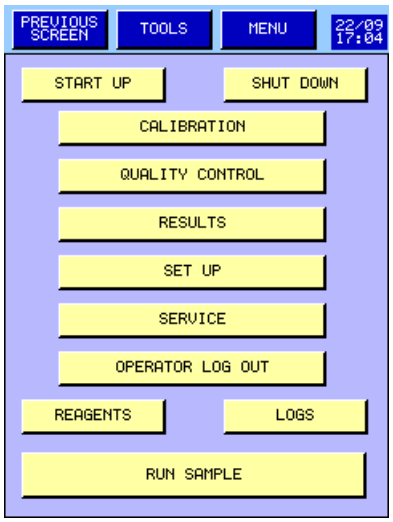
5.4 START UP RINSING



- To rinse the system before analysis, press START UP

- The cycle LED turns red. None cycle can be performed before it turns green.

- Mythic will perform 1 to 3 empty cycles to check the carry over level. This level should not to exceed the following ratios:
  - WBC : 0.5
  - RBC : 0.1
  - HGB : 0,5
  - PLT : 10

If the level is higher, **MYTHIC 18** proposes to perform a new start up or to escape. If the user chooses to escape, every result will be printed with "Start **Up not done** "message.

5.5 PREPARATIONS BEFORE ANALYSIS

The human blood venous sample must be collected in an EDTA **K3** (Ethylene Diamine Tetracetic Acid, tri potassic) tube in sufficient quantity. The LMG results are available for **six hours** after the blood draw. The use of EDTA K2 leads to a poor quality level of the LMG results.
It must be correctly homogenized before analysis. It is recommended to use a rotary agitator turning between 20 to 30 turns/mn during **10 minutes**.

	A volume of insufficient blood for the quantity of anticoagulant or a bad mixing may involve an erroneous result.

5.6 ANALYSIS

5.6.1 Introduction

	It is recommended (or mandatory according to the legislation) to carry out a Quality Control (QC) and possibly a calibration before any analysis (see section 6 & 7).

If the quality control is not carried out, it is recommended to perform two analyses on a normal sample of the day before, before beginning the series.

NOTA: The **MYTHIC 18** is delivered with a standard parameter setting described in section 3.

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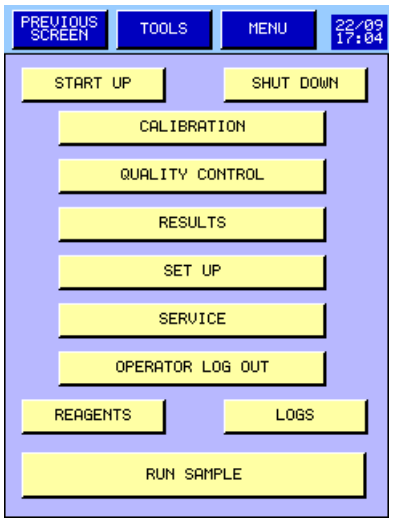
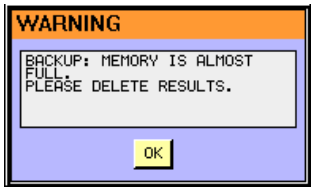
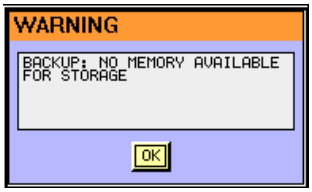
5.6.2 Sample Identification



- From the main menu, press RUN SAMPLE to reach the analysis display.

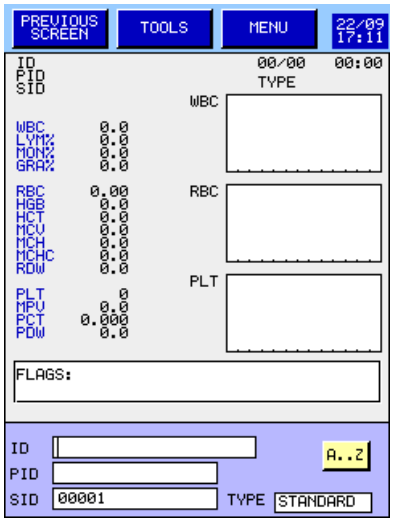


- This prompt appears when the results memory is almost full. To avoid this message, select the option FIFO mode in the set up.



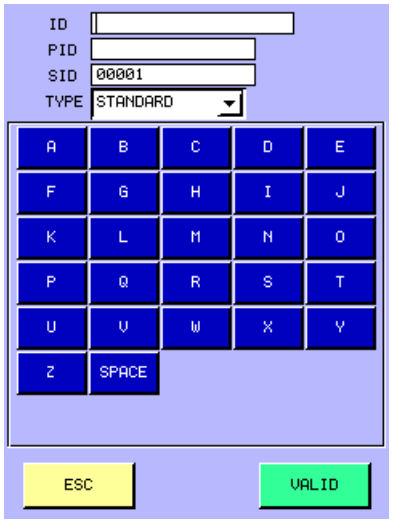
- This prompt appears when the results memory is totally full.

- To delete results see section 5.10



- The display bottom is reserved for the entry of the next sample identification to run.
- Three fields allow the entry of the identification:
  - ID: Patient Name (**20** characters max.)
  - PID: Patient Identification (**16** characters max.)
  - SID: Sample identification (**16** characters max.)

NOTA: SID number is already done. (see section 3.2).



IDENTIFICATION PROCEDURE:

- To enter or modify identification, place the cursor in the selected field with your finger or the arrow.
- To enter a figure, use the keyboard on the right of the screen, for a letter use the alphabetic keyboard by pressing A..Z.
- To accede to another character page press << or >>.
- To change the blood type, press the combo box TYPE STANDARD and select the type
- To valid the entry and return to the previous screen, press VALID.
- To return to the previous screen without validation, press ESC.

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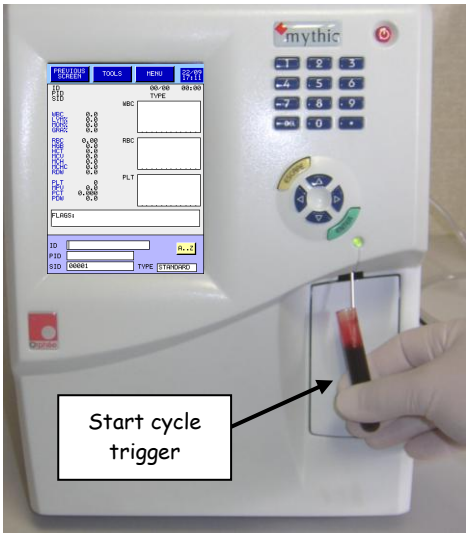
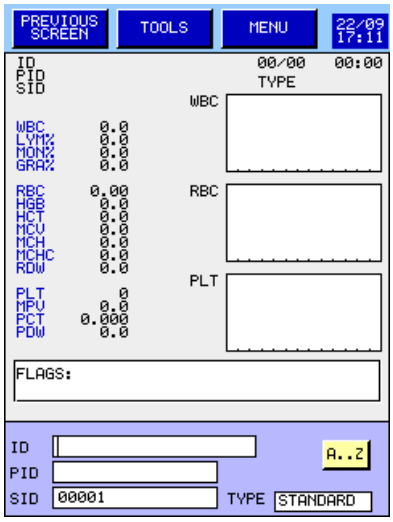
5.6.3 Sample run



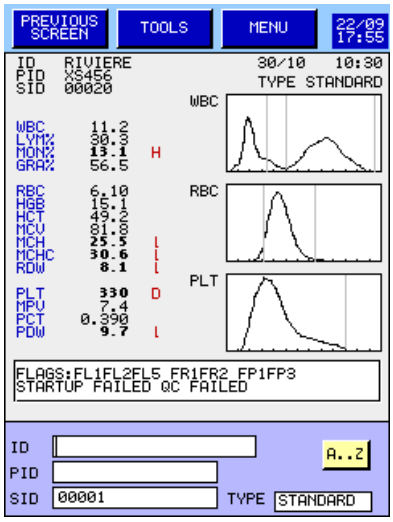
- If the needle is not visible, first presses the start cycle trigger and wait for the descent.
- Present the tube of the blood sample under the needle and press the start cycle trigger.
- The cycle LED located at the top of the needle becomes red the tube can be removed only when the needle up.
- A new cycle can be started again when it turns by again green.

	Wear rubber gloves and wash hands with a disinfectant after completion of work.



- As soon as the cycle is launched, the SID is incremented automatically and, thanks to its data processing multitasks, the **MYTHIC 18** is available for the identification of the following sample (see section 5.6.2).

5.7 RESULTS



- The results of the analysis are sent before the cycle is finished (to be checked) at the same time as the printer starts.

NOTA: It is not necessary to wait for the end of the result printing to launch a new analysis.

- The results are sent to the selected unit (see section 3).
- The information located on the right of each parameter corresponds to the indicators for out of range limits and for the rejections (see section 3).
- The curves of distribution of each cellular population are located on the right screen.
- Under the results a zone (FLAGS) is reserved for analytical alarms.
- At the bottom of the screen, there are the three inlet fields for the identification of the following sample. (See section 5.6.2).
- Press TOOLS to reprint or to resend the result.

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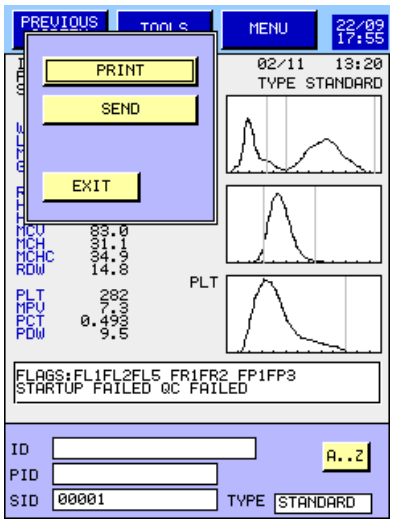


- To print the result press PRINT .
- To send the result, press SEND .
- To close the window, press EXIT .

5.8 PRINTING

Once the analysis is finished, the **MYTHIC 18** prints a result report. To modify the printing presentation or to disconnect the printer, see section [3.4.1](#).

5.8.1 Model report (A4) – external printer

EPSON LX 300+ model

ORPHEE-MEDICAL

Presentation Results MYTHIC 18

Name : AMEROLE
Comments :

Patient Id : S3487
Sample Id : 00450
Type : STANDARD

Operator ID : Date : 01/11/2004 10:01:00 Seq# : 04531

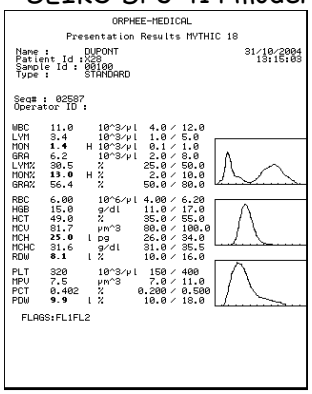
	Result	Flags	Unit	Normal limits
WBC	9.0		10^3/µl	4.0 / 12.0
LYM	3.6		10^3/µl	1.0 / 5.0
MON	**1.6**	H	10^3/µl	0.1 / 1.0
GRA	4.2		10^3/µl	2.0 / 8.0
LYM%	40.5		%	25.0 / 50.0
MON%	**13.0**	H	%	2.0 / 10.0
GRA%	**46.5**	l	%	50.0 / 80.0
RBC	5.30		10^6/µl	4.00 / 6.20
HGB	14.8		g/dl	11.0 / 17.0
HCT	45.0		%	35.0 / 55.0
MCV	88.0		µm^3	80.0 / 100.0
MCH	33.0		pg	26.0 / 34.0
MCHC	32.0		g/dl	31.0 / 35.5
RDW	12.1		%	10.0 / 16.0
PLT	350		10^3/µl	150 / 400
MPV	8.6		µm^3	7.0 / 11.0
PCT	0.325		%	0.200 / 0.500
PDW	12.2		%	10.0 / 18.0

FLAGS:FL1FL2

Comments :

5.8.2 Model report – Ticket printer

SEIKO DPU 414 model



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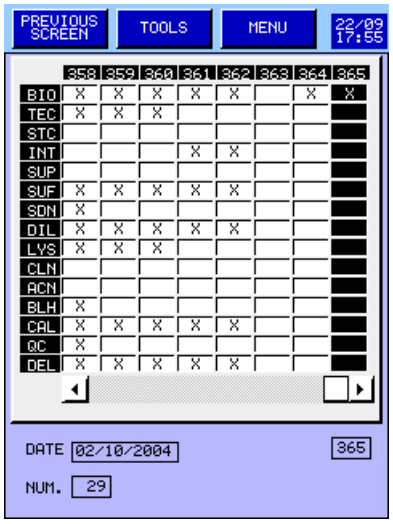
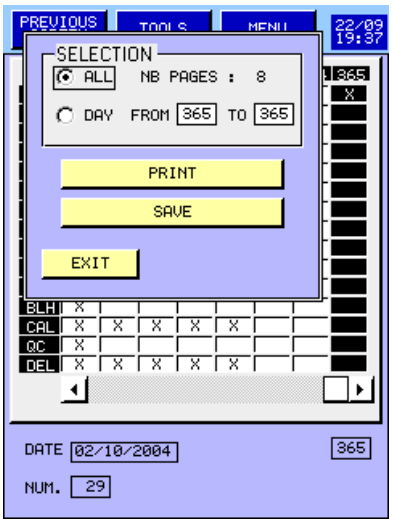
5.9 LOGS

From the main menu, press LOGS to reach the logs display

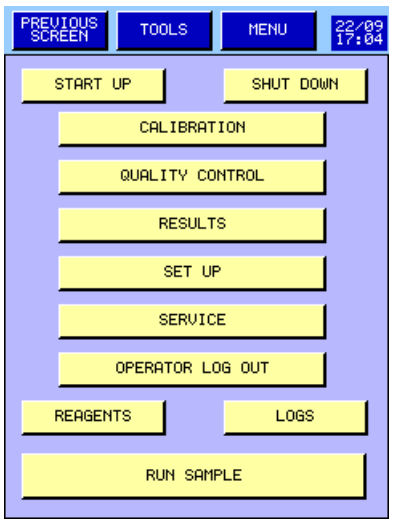


- **MYTHIC 18** manages a simplified log allowing to save and display all the events done for the following actions:
  - **BIO**: Login with the Biologist code.
  - **TEC**: Login with the service Technician code.
  - **STC**: Login with the "Super" service Technician code.
  - **INT**: An intervention or maintenance has been performed.
  - **SUP**: Start Up cycle has been performed.
  - **SUF**: Start Up cycle has failed.
  - **SDN**: Shut down cycle has been performed.
  - **DIL**: Diluent replacement.
  - **LYS**: Lysis replacement.
  - **CLN**: Cleaner replacement.
  - **ACN**: Auto cleaning cycle.
  - **BLH**: Bleach cycle.
  - **CAL**: Calibration.
  - **QC**: Quality control.
  - **DEL**: Results deleted in Archive.
  - Each column is identified by a number (recall at the right bottom of the screen 365). In the bottom of the screen is displayed the date DATE 02/10/2004 and under it the number of analysis NUM. 29 run during this day.



  - - To print the log report press TOOLS
  - - Select ALL to print the logs of the number of pages indicated on the screen.
  - - To print the logs of one or more days select DAY then enter the day reference number.
  -
  - SAVE allows to save the log file in an USB key.

5.10 ARCHIVE



MYTHIC 18 can save more than the last 1000 patients with results, alarms, distribution curves.

- Press RESULTS to enter the archive display.

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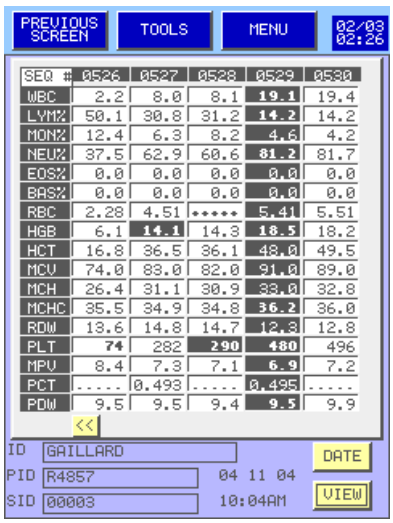
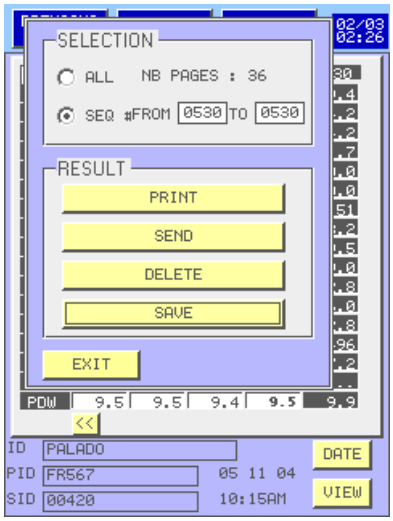
5.10.1 Results

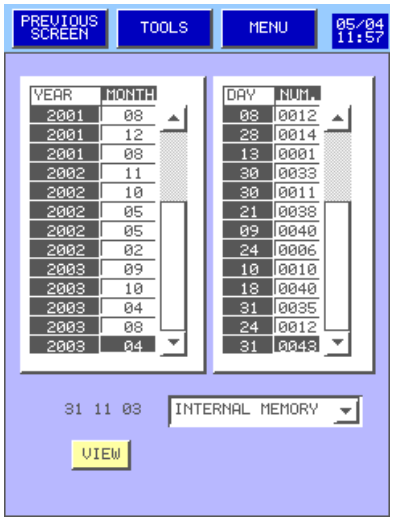


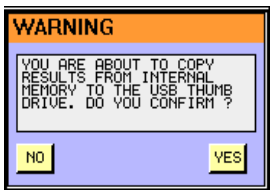
- The Archive display allows viewing the results of the analysis.
- The first column presents the name of the different parameters, the first line the result number.
- The results of the patients are presented in column.
- At the bottom of the display, under the table, the **ID**, **PID**, **SID**, **SEQ** number, date and time of the selected patient (dark background) are presented for each result selected.
- The button << >> , located under the table, allows changing pages.
- To find a result in the list, select the **SEQ** number wanted, press RES
- To view an entire result, select the **SEQ** number wanted, press VIEW
- To print, send, delete or save (in an USB key) results press TOOLS
- DATE allows to accede to the results date list.



- It is possible to print, send, delete or save (in a USB key) :
  . All results: Press ALL
  . NB PAGES : 36 for printing.
  . Selected results: Select the first and the last results:
  SEQ #FROM 0530 TO 0530
- Then press on PRINT SEND DELETE or SAVE

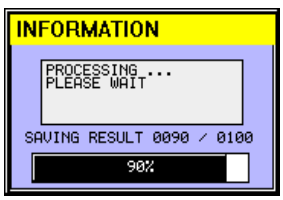
NOTA: the printed report is a **list** of all selected patients.





- This prompt appears to confirm the storage in the USB key.

If you press YES the selected results will be deleted from the internal memory and stored in the USB key.



- This prompt allows to following the storage.

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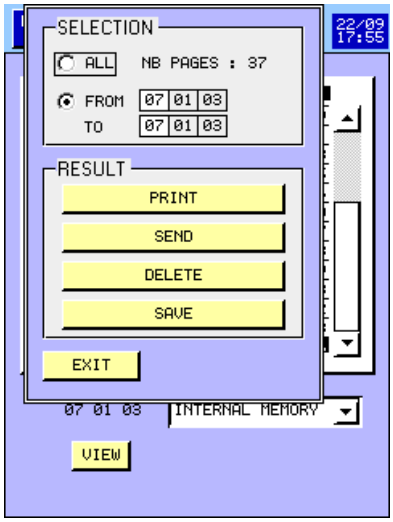
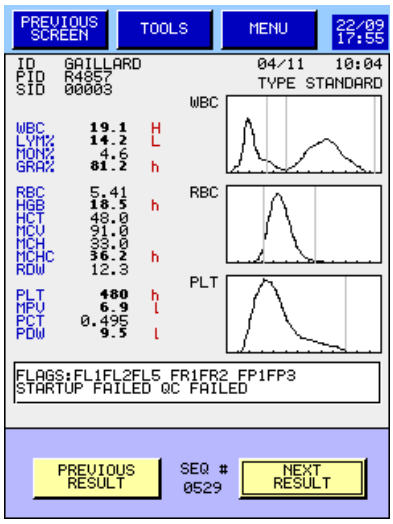
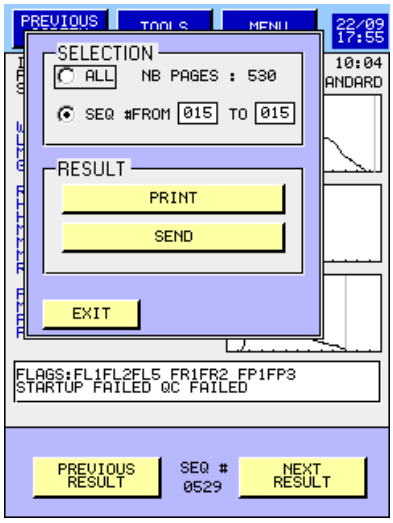


- To print, send, delete or save results per day press TOOLS
- It is possible to print, send, delete or save:
  - . All results of the same month: Press ALL
  - . Between two days of the same month: press FROM 14 02 03 TO 14 02 03
- The printed report is a list of all selected results between the two days.

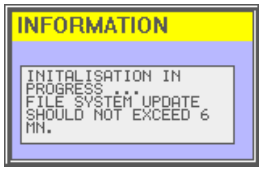
5.10.2 View



- Keys PREVIOUS RESULT and NEXT RESULT allow displaying each result and its identification.
- To print, send or delete a result, press TOOLS
- The printed report is full page with one or two results per page.
- To come back to the archive main page, press PREVIOUS SCREEN.
- To come back to the Main Menu press MENU.



- To print or send a result, press TOOLS
- It is possible to print or send:
  - . All results: Press ALL
  - . Selected results: Select the first and the last results:
    - SEQ #FROM 0526 TO 0526
- To delete a result come back to the list display.



This message appears when you exit the result screens and it could stay up to 3' to enable the update of all the files.

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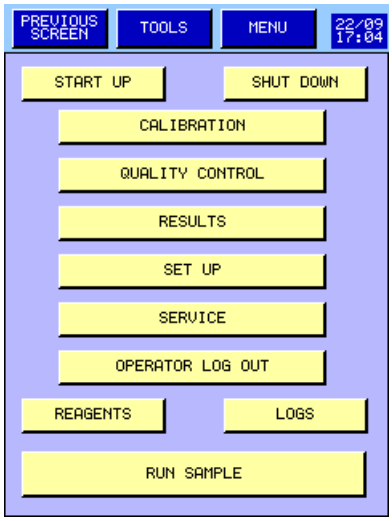
5.11 STAND BY AND SHUT DOWN



- From the main menu, press SHUT DOWN. **MYTHIC 18** automatically perform a shut down cycle.
- All the hydraulic circuits are rinsed, and then cleaned with the cleaning solution.
- At the end of the cycle, **MYTHIC 18** automatically stop.
- Shut Down can be automatically performed after a setting time (see section 3.4.6)

NOTA: After a shut down, it is impossible to perform an analytical cycle without launching a start up cycle. (See section **5.2**)

MYTHIC 18 must stay at rest with cleaning solution during three hours every 24 hours.

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6. QUALITY CONTROL

6.1 INTRODUCTION

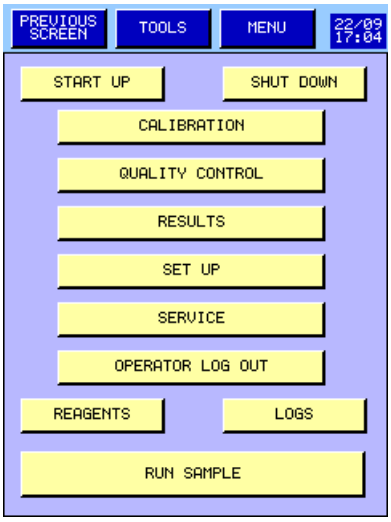
Quality control allows checking the stability of the **MYTHIC 18** analytical performances when operating.

	The control blood must be used before its expiry date and stored according to the manufacturer instructions for use. It must be well-mixed before use.

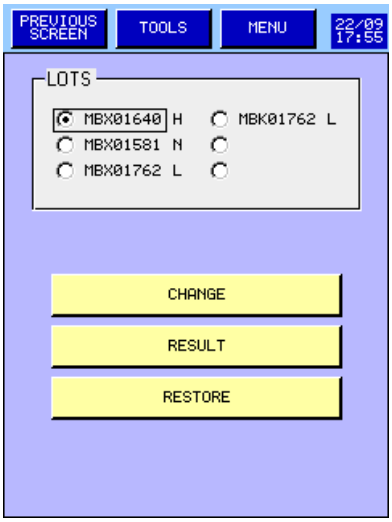
In case of no local regulation, it is recommended to run a control blood at the beginning of each working day before running sample.
In case of exceeding the tolerances indicated on the blood control result sheet, it is recommended to perform a calibration (see section 7).

6.2 QC

MYTHIC 18 stores in memory, up to 100 results per lot for 6 different lots. Results of each lot can be viewed in tables and Levey-Jennings graph.



- Press QUALITY CONTROL to have access to the quality control menu.



- Quality control display presents the identification of the lots.
- The last active lot is labeled with a dark dot on the left lot.
- To choose another lot, press on the wished lot.
- The key CHANGE allows the modification of the identification and the target values.
- The key RESULT allows:
  . To view the result table.
  . To perform quality control analysis.
- The key RESTORE allows restoring the data from a USB key (results and targets) see section 6.2.4.
- To print or send the targets, results and graphics press TOOLS.

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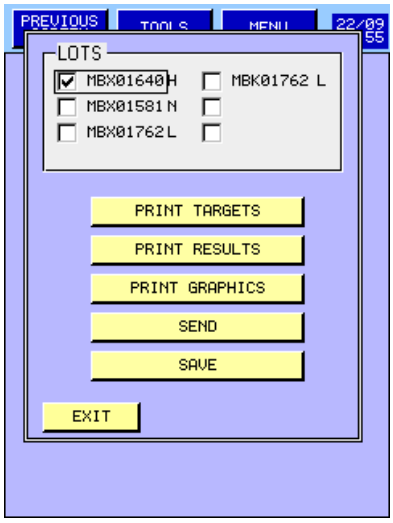
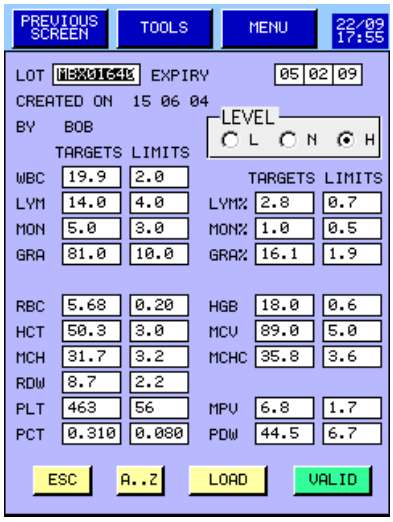


- Tag the lot number to select then press the appropriate button.

- SAVE allows to save the targets, results and graphics in the USB key.

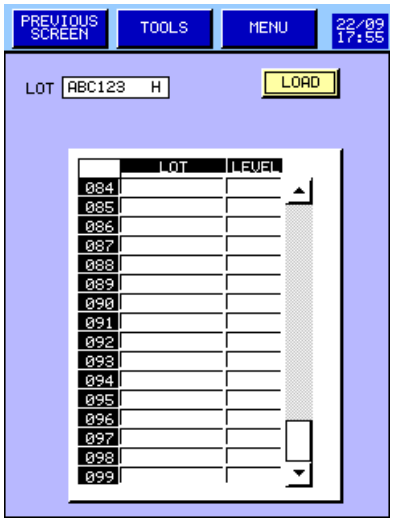
6.2.1 Change



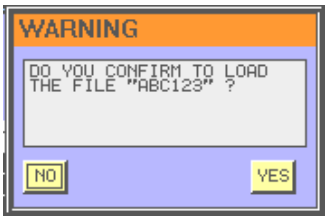
- In this display, the user can enter the:
  - Lot number
  - Expiry date
  - Target values and tolerances
  - Level

- Press ESC to delete the modifications you made.
- Press VALID to validate your modifications or the loading.
- Press A..Z to change the Lot number.
- To print the targets and limits come back to the previous display.
- Press LOAD to load the target and tolerances values, the lot number and expiry date from a USB key.

NOTA: All the results in memory linked with the control lot number will be cleared as soon as the validation is confirmed.



- Press LOAD to load from a USB key all the information about a new lot of calibrator.



- Press YES if you are sure to load the choice file.

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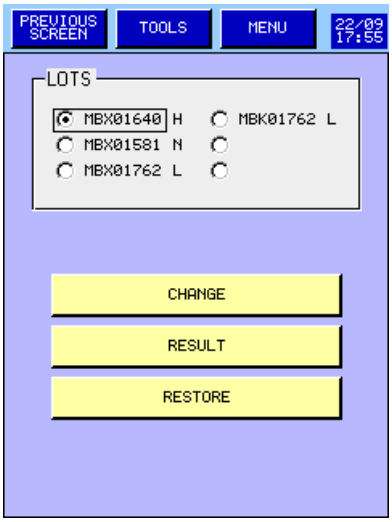
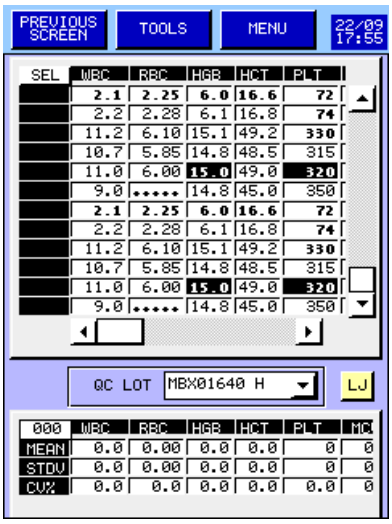
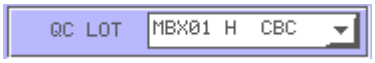
6.2.2 Run control blood

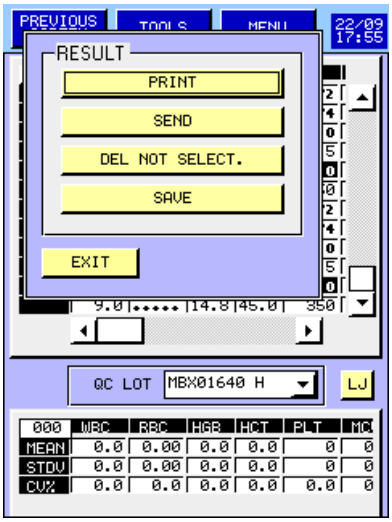


- Press RESULT to run the control blood.

	Before to run the control, check and clean the opening of the cover enabling the descent of the needle, to avoid any fall of dry blood particles inside the control tube


PREVIOUS SCREEN
TOOLS
MENU
22/09 17:55
SEL WBC RBC HGB HCT PLT
QC LOT MBX01640 H
LJ
000 WBC RBC HGB HCT PLT MC
MEAN 0.0 0.00 0.0 0.0 0 0
STDV 0.0 0.00 0.0 0.0 0 0
CV% 0.0 0.0 0.0 0.0 0.0 0

- To run quality control analysis:
  - Press Results.
  - Present the control blood under the sampling needle.
  - Press the start cycle trigger.
- The cycle LED located at the top of the needle flickers alternatively of red with green, when it becomes red the tube can be removed.
- Repeat this operation as long as needed.
- The results are displayed in line run after run.
- The statistic calculations are shown at the bottom of the display and are automatically done after each run.
- The cursor allows displaying results for the other parameters
- The window  allows access to the results in memory for another blood control lot.
- The column allows to validate or to unselect a result.



- To print, send, delete or save (in a USB key) a result, press TOOLS

- Press LJ to open the Levey-Jennings graph screen.

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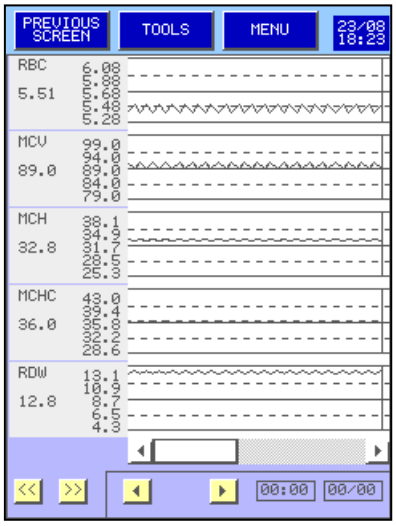
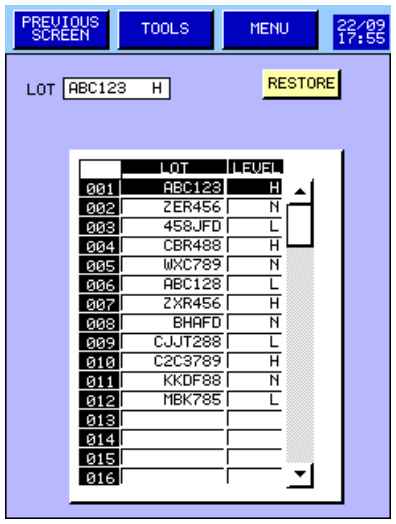
6.2.3 Levey-Jennings graph

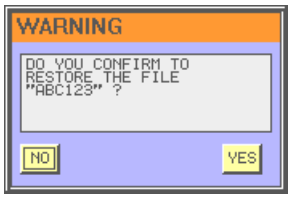


- This menu enables to display the Levey-Jennings graph for each quality control run.
- The column on the left shows each parameter with the target values and the limits. The value under the name of the parameter is the value where the cursor is located on the graph.
- The keys << and >> enable to display the other results.
- The cursor located under the graph enables to display all the registered results.
- The keys 076 enable to move the cursor, the number is the number of the result
- 00:00 00/00 give the date and the time of the displayed result.

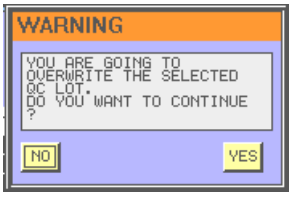
6.2.4 Restore



- This menu enables to restore all the information (results and targets) for the file selected from the USB key to the internal memory.

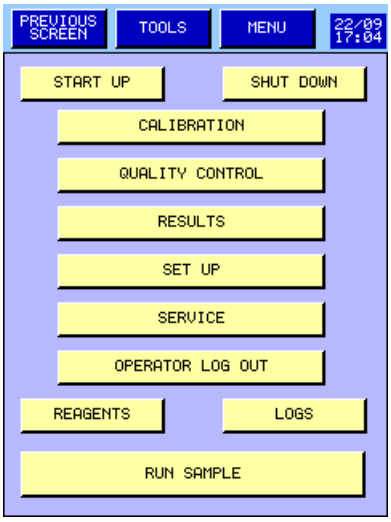


- Press YES if you are sure to load the selected file.



	All the information of the selected file will be overwrite by the one coming from the USB key.

6.3 REPEATABILITY



- To run repeatability, press first SERVICE

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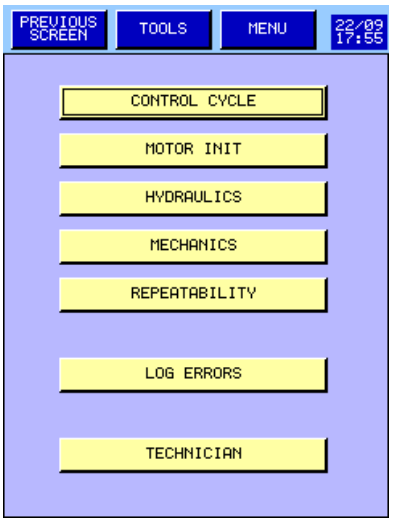
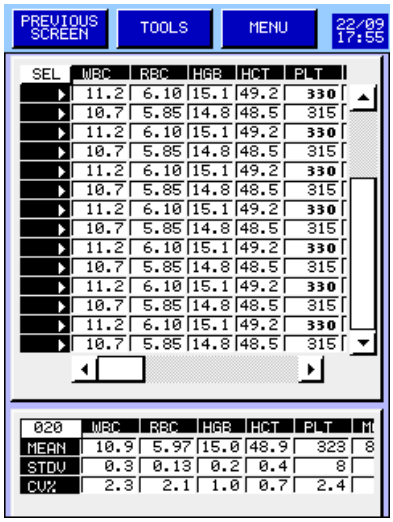
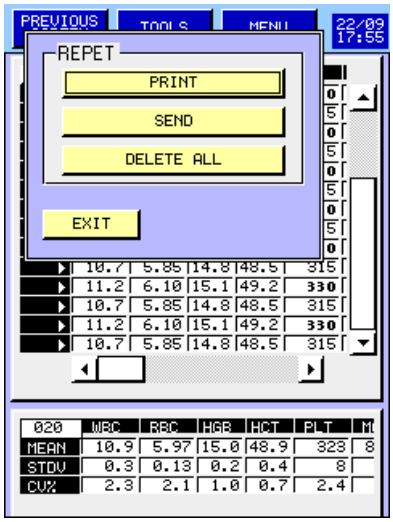


- The key REPEATABILITY allows having access to the repeatability display.


PREVIOUS SCREEN
TOOLS
MENU
22/09 17:55
SEL WBC RBC HGB HCT PLT
020 WBC RBC HGB HCT PLT N
MEAN 10.9 5.97 15.0 48.9 323 8
STDV 0.3 0.13 0.2 0.4 8
CV% 2.3 2.1 1.0 0.7 2.4

This screen allows carrying out a test of repeatability on all the parameters measured by the **MYTHIC 18**.

- Present the sample under the sampling needle and press in the trigger located behind the needle.
- The cycle LED located at the top of the needle flickers alternatively of red with green, when it becomes red the tube can be removed.
- Repeat the operation as many times as desired (maximum **20** runs).
- The results are progressively sent on line in the table.
- Statistical calculations are automatically carried out with each run.
- The cursor located between the two tables enables to send the other results (the results of statistical calculations move at the same time).
- The column SEL allows to validate or to unselect a result.



- The key TOOLS allows carrying out the following actions:
  - Print the table.
  - Send the results.
  - Delete the results.

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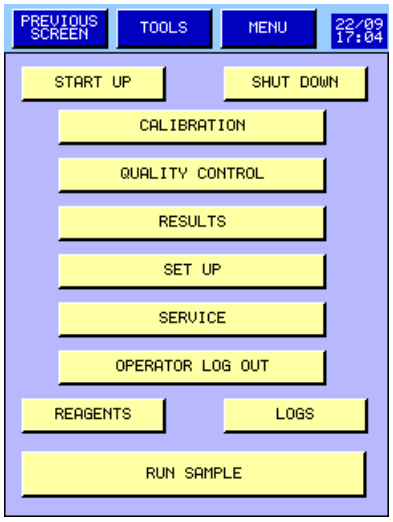
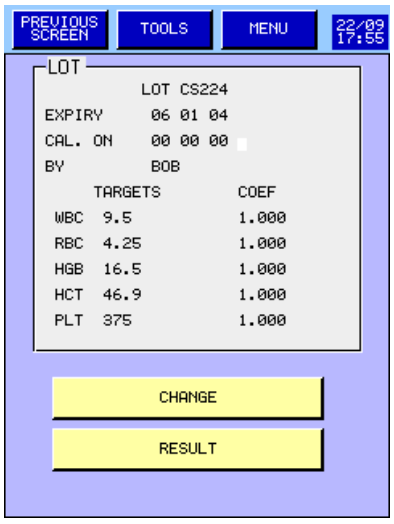
7. CALIBRATION

	The calibration of the MYTHIC 18 should be carried out only if the QC carried out on a blood control used under the recommended conditions, is out of the limits to a significant degree (see section 6).

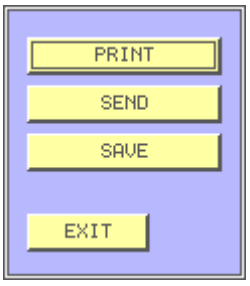
	The calibration blood must be used before its expiry date, be mixed and stored in accordance with the instructions of use recommended by the manufacturer.



- To reach the screen Calibration, press the key CALIBRATION from the main menu.



- This menu sends the following information:
  - Lot number of the last used calibrator.
  - The expiry date of the current lot.
  - The last date of calibration.
  - The operator name.
  - The target values.
  - The current coefficients of calibration.



- Press TOOLS to print, send or save (in a USB key) all these information.

- To enter new values or to modify the values, press CHANGE.

- To calibrate, press RESULT.

NOTA: If the **M** letter appears on the right of the date of calibration, that means that the last calibration was done by modification of the calibration factor (see section 3.4.5)

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Model of print out calibration report:

CALIBRATION IN PROGRESS SERIAL NUMBER: 000000-000000
SOFT VERSION V0.5.x

PRINTED ON : 19/06/2004 15:50:00 BY BILL

COEFFICIENTS : 1.000 1.000 1.000 1.000 1.000

LOT CS224
CREATED ON 18/12/2003 BY BILL
EXPIRY 06/01/2004

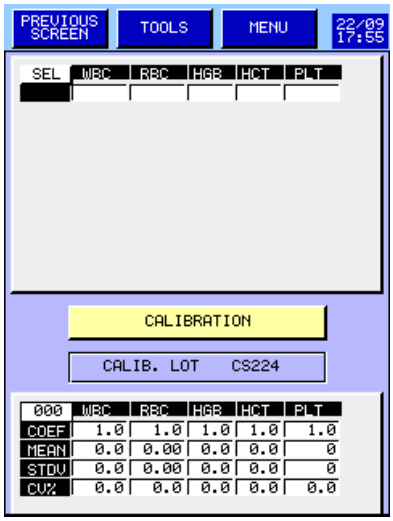
	WBC	RBC	HGB	HCT	PLT
TARGETS	9.5	4.25	16.5	46.9	375
LIMITS	1.0	0.24	0.5	2.1	25

COEF	1.0	1.0	1.0	1.0	1.0
MEAN	0.0	0.00	0.0	0.0	0
STDV	0.0	0.00	0.0	0.0	0
CV%	0.0	0.0	0.0	0.0	0.0

7.1 RESULTS

7.1.1 Calibration blood analysis

This screen allows carrying out analysis on calibration blood to perform the **MYTHIC 18** calibration.



- Present the calibration tube under the sampling needle and press the trigger behind the needle.
- The cycle LED located at the top of the needle flickers alternatively of red with green, when it becomes red the tube can be removed.
- The results are progressively sent on line in the table.
- Repeat the operation as many times as desired (maximum **10** runs).
- Statistical calculations are carried out automatically with each run.
- The window CALIB. LOT CS224 located between the results and the statistical calculation reminds the lot number of the calibrator.
- The column SEL allows to validate or to unselect a result.
- To calibrate press CALIBRATION or TOOLS.

Before to run the calibrator, check and clean the opening of the cover dedicated to the down of the needle to avoid any fall of dry blood particles inside the calibrator tube

NOTA: The results of the analyses carried out on one calibrator during the same day remain with the screen and are used in calculations if they are selected.

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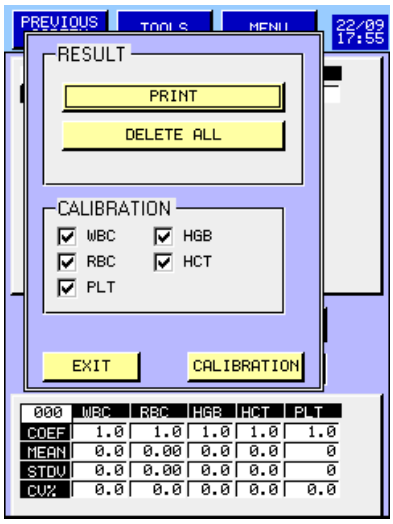
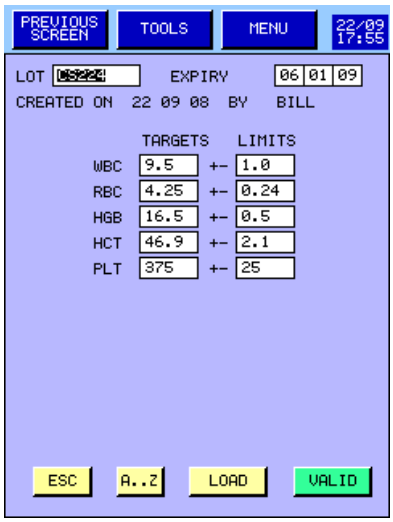
7.1.2 Calibration



Before to start the calibration, unselect the results which you do not wish to use for the calculation of the calibration (see below section 7.1.1).

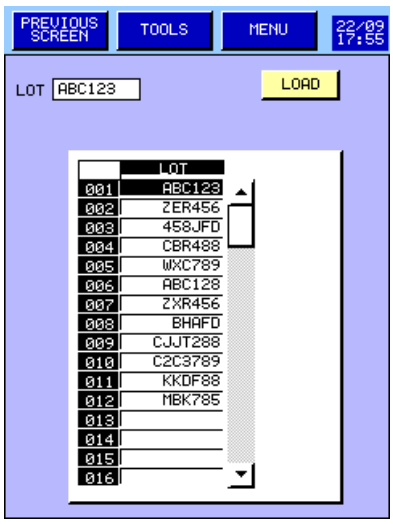
- The key CALIBRATION or TOOLS allows:
  - To calibrate with the selected results.
  - To delete the results. Press DELETE ALL
  - To print the results. Press PRINT (see below the print report)
- To calibrate one or more parameters:
  - Select the parameter
  - Press the key CALIBRATION

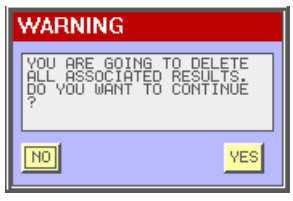
7.2 TARGET VALUE MODIFICATIONS



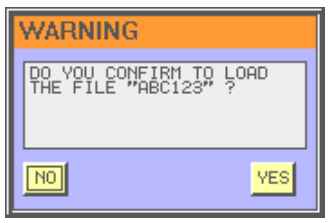
- To modify information relative to a batch or to create a new batch, please follow the following steps:
  - From **Calibration Menu**, press CHANGE.
  - Select the lot number LOT CS224
  - To modify the lot number press A..Z
  - Select the field to be modified.
  - Enter your new value with the numerical keyboard or with the alphabetical keyboard.
  - Press VALID to validate your modifications.
  - Press ESC to leave the menu without modification.

Any modification (lot number, date or target values) involves the deletion of all the associated results always in memory.





- Press LOAD to load from a USB key all the information about a new lot of calibrator.



- Press YES if you are sure to load the right file.

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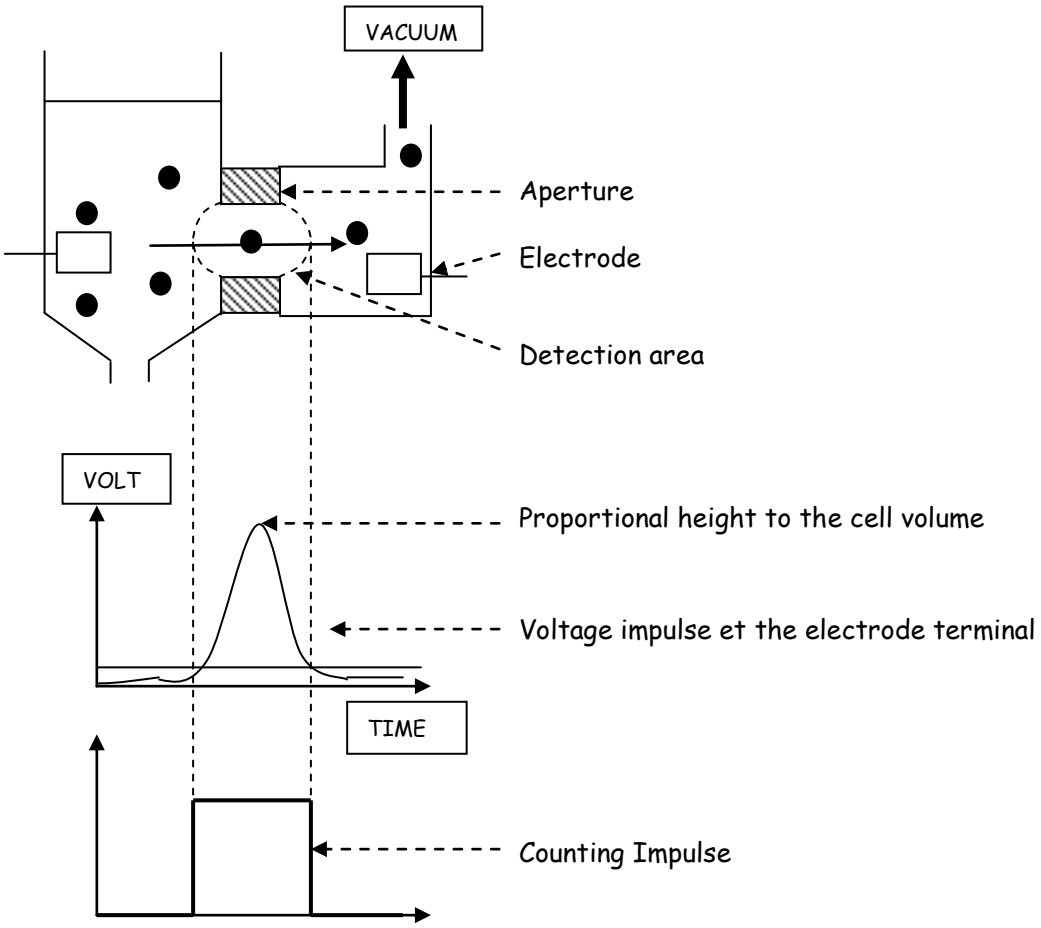
8. TECHNOLOGY

8.1 DETECTION PRINCIPLE

8.1.1 WBC, RBC, PLT Counting

The counting of the cellular elements in a blood sample is done with the impedancemetry technique.
This technique is based on the modification of the impedance of a calibrated aperture soaking in an electrolyte and going through a constant course delivered by two electrodes located on both sides of the aperture.
A vacuum applied on a side of the aperture allows the cells passage. They oppose their physical volume to the course passage. A voltage impulse is registered at the electrodes terminal. The height of this impulse is proportional to the cell volume.



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8.1.2 Hemoglobin measurement

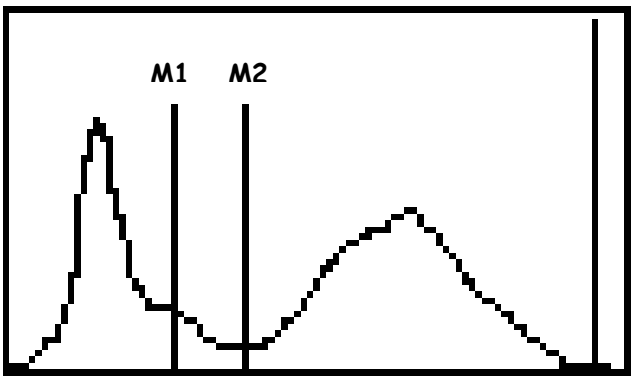
The hemoglobin measurement is directly done in the WBC chamber, by spectrophotometry at 555 nm. Hemoglobin is detected by formation of a chromogen cyanmethemoglobin type, for lytic solution with cyanide and oxyhemoglobin for lytic solution without cyanide.
A measurement of the blank of hemoglobin is done for each analytic cycle and during the start up rinsing step.
An automatic offset circuit for the LED 555 nm allows to maintain the blank level at the same range. It is not necessary to adjust this range with a potentiometer.

8.2 LEUCOCYTE ANALYSIS

The leukocyte analysis is done by impedancemetry in the WBC counting chamber, seven parameters are obtained :

Parameters		Pathologies (adjustment section 3.4.4.1)
WBC	White Blood Cells	Leukocytosis : WBC>WBC h Leucopenia : WBC<WBC b
LYM%	Lymphocytes in percentage	Lymphocytosis : LYM>LYM h (% &/or #)
LYM#	Lymphocytes in value	Lymphopenia : LYM<LYM b (%&/or #)
MON%	Monocytes in percentage	Monocytosis : MON>MON h (%&/or #)
MON#	Monocytes in value	
GRA%	Granulocytes in percentage	Granulocytosis : GRA > GRA h (%&/or #)
GRA#	Granulocytes in value	Ganulopenia : GRA < GRA b (%&/or #)

The formula approach is obtained by WBC distribution curve analysis after action of the lytic reagent. This reagent destroys the RBC and their stromas and acts on the white blood cell cytoplasmic walls.



In this case, lymphocytes are between the beginning of the curve and M1, monocytes between M1 and M2 and granulocytes higher than M2.
When the WBC result is lower than $1{,}0 \times 10^3/mm^3$ the lymphocytes, monocytes and granulocytes results and the curve do not appear.

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8.3 ERYTHROCYTE ANALYSIS

The erythrocyte analysis is done by impedancemetry in the RBC counting chamber and by analysis of the hemoglobin inside WBC chamber as previously described. Seven parameters are obtained:

Parameters		Pathologies (adjustment section 3.4.4.1)
RBC	Red Blood Cells	Erythrocytosis : RBC>RBC h
HGB	Hemoglobin	Anemia : HGB < HGB b
HCT	Hematocrit	
MCV	Mean Corpuscular Volume	Microcytosis : VMC<VMC b Macrocytosis : VMC>VMC h
MCH	Mean Corpuscular Hemoglobin	
MCHC	Mean Corpuscular Hemoglobin Concentration	Hypochromia : MCHC<MCHC b Cold Agglutinin : MCHC>MCHC h
RDW	Red blood cells Distribution Width	Anisocytosis 1 : RDW>RDW h1

Hematocrit (**HCT**) is measured by integration volume of all of the red blood cells which flow in the RBC counting chamber aperture.
MCV is obtained by calculation, following the formula:

$$\textbf{MCV} = \frac{\text{HCT} \bullet 10}{\text{RBC}}$$

The RBC distribution curve analysis allows the measurement of **RDW**. RDW is an expression of the standard deviation compared to MCV. This parameter evaluates the RBC anisocytosis.

$$\textbf{RDW} = \frac{k \bullet SD}{MCV}$$

Wintrobe constant calculation:

The Mean Corpuscular Hemoglobin (MCH) calculation is made from HGB and RBC by the formula below

$$\textbf{MCH} = \frac{\text{HGB} \bullet 10}{\text{RBC}}$$

The Mean Corpuscular Hemoglobin Concentration (MCHC) is made from HGB and HCT by the formula below :

$$\textbf{MCHC} = \frac{\text{HGB} \bullet 100}{\text{HCT}}$$

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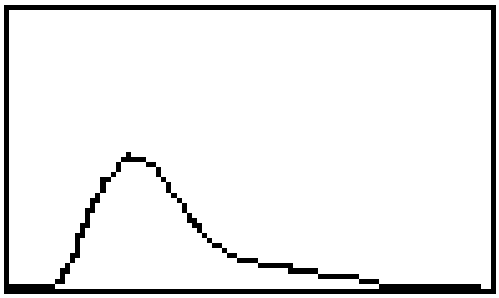
8.4 ANALYSIS OF PLATELETS

Platelet analysis is made by impedancemetry in the RBC counting chamber at the same time with red blood cells. Four parameters are obtained :

Parameters		Pathologies (adjustment section 3.4.4.1)
PLT	Platelets	Thrombopenia : PLT<PLT b Thrombocytosis : PLT>PLT h
MPV	Mean Platelet Volume	Giant platelets : MPV> MPV h
PDW	Platelet Distribution Width	
PCT	Thrombocrit	

The analysis of the platelet distribution curve allows measuring the Mean Platelet Volume (**MPV**) and the Platelet Distribution Width (**PDW**).



Thrombocrit (**PCT**) is made from PLT and MPV by formula below:

$$\mathbf{PCT} = \frac{PLT \bullet MPV}{10000}$$

8.5 ALARMS

MYTHIC 18 manage 17 different alarms. These alarms allow the user to be alerted if there is a mistake which can affect the quality of the results. All of these alarms appear on the right of the result.

	In presence of one or more alarms, it is recommended to check the result by a conventional measure or on blood smear.

NOTA : Most of these alarms can be modified by the user (see section 3).

8.5.1 General Flags

The following alarms are common for all parameters.

*****: Counting or measure rejection. Can appear with WBC, RBC, PLT and HGB (see section 8.5.3 for HGB)

XXX**D**: Higher than linearity limits but lower than the reportable limits. WBC, RBC, PLT, HCT, HGB.

+++D: Higher than the reportable limits. WBC, RBC, PLT, HCT, HGB.

----: Rejected value.

h: results higher than normal value.

b: results lower than normal value.

H: results higher than panic value.

B: results lower than panic value.

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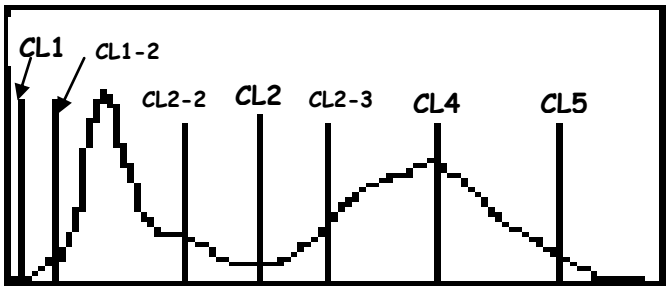
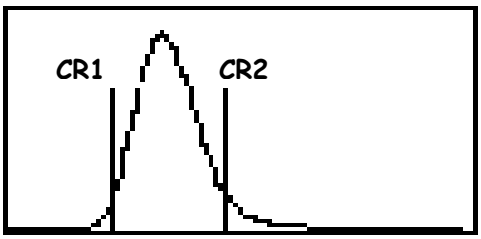
8.5.2 Leukocytes Flags



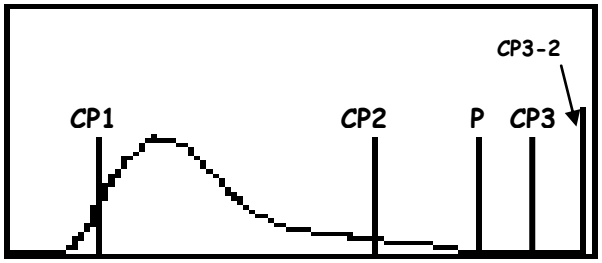
L1 = **CL1** to **CL1-2**: Platelet aggregate or erythroblast
L2 = **CL2** to **CL2-2**: Presence of Myelocytes, lymphoblast or basophiles.
L3 = **CL2** to **CL2-3**: Presence of eosinophils, myelocytes.
L4 = **CL4** Granulocyte volume too low
L5 = **CL5** to the end: Presence of large size cells.

8.5.3 Erythrocyte and HGB Flags



R1 = **CR1**: Abnormal quantity of microcytes at the left side.
R2 = **CR2**: Abnormal quantity of macrocytes at the right side.
HGB: * means bad measure of the HGB blank.

8.5.4 Platelet Flags



P1 = **0** to **CP1**: Presence of abnormal quantity of debris or small cells.
P2 = **P** to **CP2**: Presence of schizocytes.
P3 = **CP3** to **CP3-2**: Presence of microcytes.

8.5.5 Machine Flags

INS_T = Means that the working temperature is lower than 17°C or higher than 33°C and the result could be affected.
INS_P = Means that the vacuum counting is out of range, if the flag appears at each cycle, please contact your Orphée's representative.

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8.6 HYDRAULIC DESCRIPTION

The hydraulic part of the **MYTHIC 18** is very simple and made of only three modules:

- Sampling module.
- Counting bath module.
- Syringes module.

The modules are connected together by semi rigid tubing.

8.6.1 Sampling module

This module (patent pending) enables to draw the sample and to perform the WBC and RBC/PLT dilutions.
It is assembled with a rotating rocker moving around a support which maintains the system to move up and down the sampling needle.
A very reliable system of rack-gear moves the rocker.
The cleaning system of the sampling needle can be removed without tool (see section **9.3.2**).
The o-ring of the needle included in the cleaning system can also be removed without tool (see section **9.3.2**).
The maintenance of these parts is very easy to perform.

8.6.2 Counting bath module

This module allows to count the WBC and RBC/PLA and to measure the HGB.
It is made with a manifold maintaining the reagent commutation valves and the counting bath block with their measurement block including the apertures.
The counting bath block assembly and these apertures can be removed without tool (see section **9.3.3**/**4**/**5**).

8.6.3 Syringes module

This module (patent pending) enables:

- to draw the sample
- to distribute the reagents
- to drain the baths
- to do the vacuum necessary for counting
- and to push the waste to the waste container.

It is made with a manifold maintaining the fluid commutation valves and with the syringes bloc including five syringes:

- The sampling syringe
- The lysis syringe
- The two waste and vacuum/pressure syringes
- And the diluent syringe.

Only one motor drives the five syringes.
The diluent input and the waste output are also included in this manifold.

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8.7 SOFTWARE

8.8.1 Windows

Common keys:

This three keys

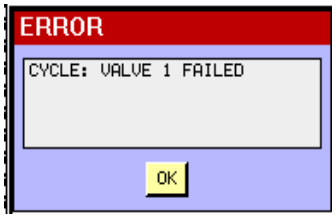
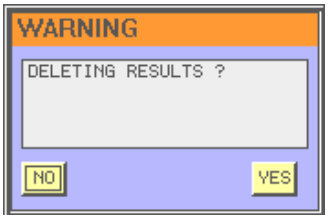
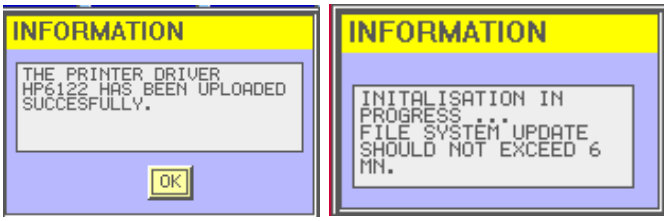
are always present in all screen

allows to come back to the previous display.

allows to come back to the MENU display where ever you are in the arborescence.

depends on the screen it allows to open a window dedicated to perform an action, for example to select information, to print, send or delete it.

Windows:

		
Means an **ERROR** occurred, it is mandatory to do the action describe in the window or in the table section 9.6.	**WARNING**: You have to confirm or not the action describe in the window.	**INFORMATION** window.

8.8.2 Menu tree

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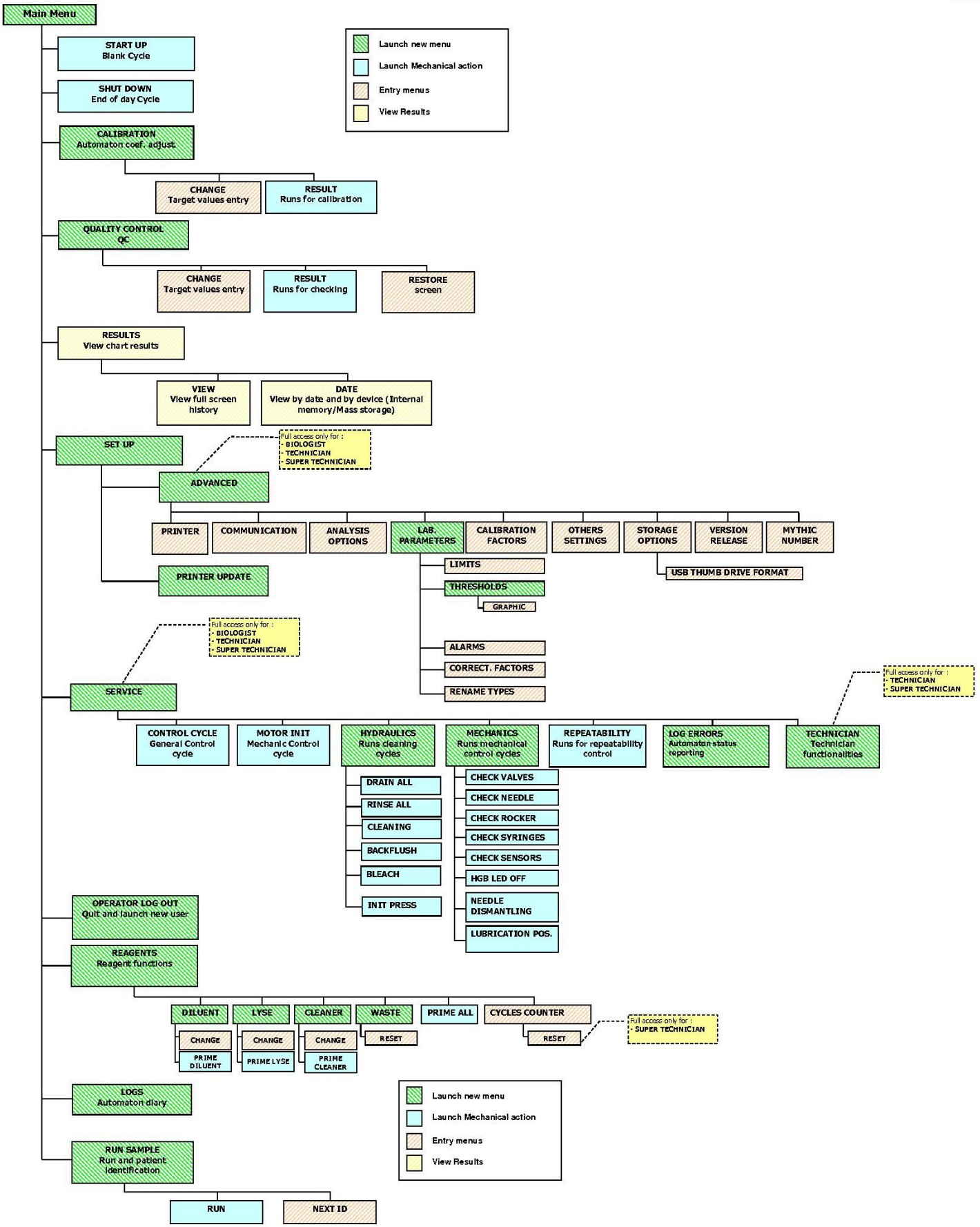

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9. SERVICE

The quality of the results and the reliability of the **MYTHIC 18** are directly linked to the strict respect of the maintenance hereafter described.

To perform the maintenance and the repair described in this section, it is mandatory to have received adequate training, to wear rubber gloves and wash hands with a disinfectant after completion of work.

9.1 MAINTENANCE

9.1.1 Maintenance table

NOTA: This table is made for an average number of 50 samples per day. For more, please increase proportionally the number of maintenances.

MAINTENANCE	DAILY		WEEKLY		MONTHLY		HALF A YEAR		ANNUALLY	
	User	Tech	User	Tech	User	Tech	User	Tech	User	Tech
Reagents level	X									
Start Up	X									
Automatic cleaning	X									
Concentrate cleaning					X					
Shut down	X									
Cover cleaning	X									
Piston greasing							X			X
Needle greasing							X			
Needle o-ring replacement										X
Syringes o-ring replacement										X
Motor screw greasing										X

- Reagents level control: see section **5.1**
- Start up: see section **5.2**
- Automatic Cleaning: The cleaning is automatically performed by the **MYTHIC 18** following the set up defined by the user (see section **3.3.6**). (the standard value is 80).
Increase the frequency of the cleaning of the **MYTHIC 18** in case of analyzes of pathological samples or if there are too many flags and too often.
- Concentrated cleaning: see section **9.1.1**
- Shut down: see section **5.11**
- Cover cleaning: Clean the cover above and around the sampling needle with a wet paper with a disinfectant to eliminate the blood trace.
- Piston greasing: see section **9.1.3**

9.1.2 Concentrate cleaning

This cleaning is necessary when **MYTHIC 18** is in permanent rejection for one measured parameter.
Prepare a Sodium Hypochlorite solution at 12° in chloride (or 3.6%) (diluted 4 times with distilled water if sodium hypochlorite is concentrated at 48° in chloride or three times with 36°).

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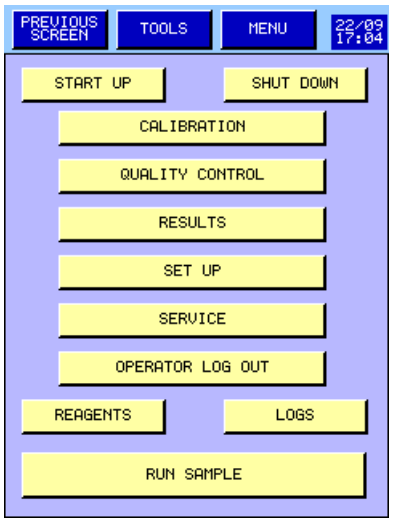
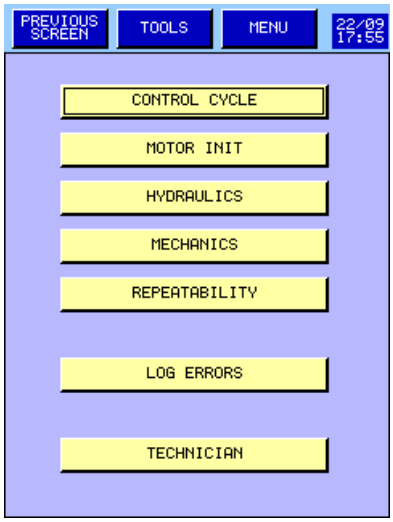
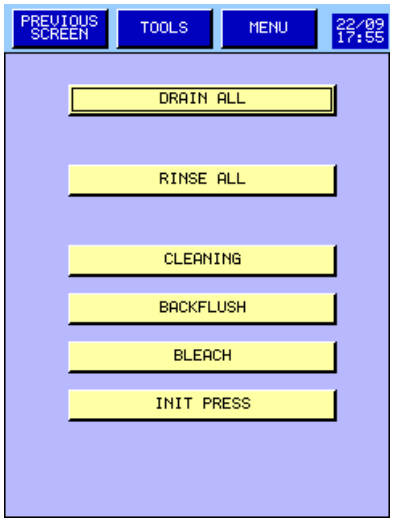


- Return to the main menu by pressing MENU.
- Then press SERVICE.



- Press HYDRAULICS.



- Press BLEACH to start the cycle (drain the counting chamber).

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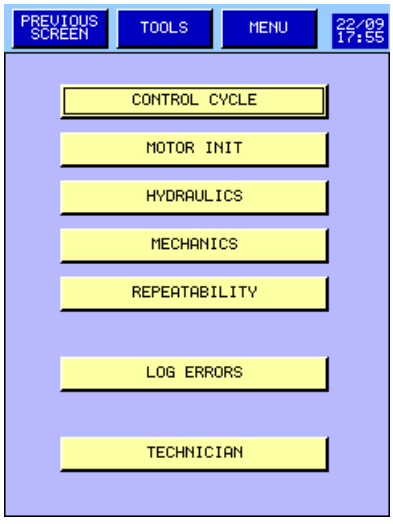
Wear rubber gloves and wash hands with a disinfectant after completion of work.

- Wait for the information window and then
- Open the door on the right side (see section 1.1.3).
- Put 2 ml of sodium hypochlorite solution (12° or 3.6%) in each counting chamber.
- Press the button in the window located in the screen center.
- **MYTHIC 18** perform a maintenance cycle of the apertures follow with a standby mode during 2 min.
- After 2 min. **MYTHIC 18** rinses all of the elements.

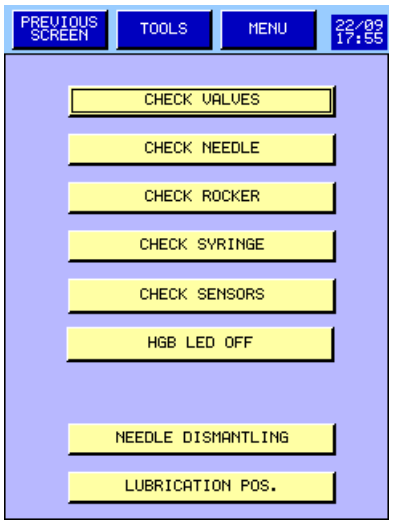
Perform a blank cycle before to run any analytic cycle

9.1.3 Piston greasing



- To have access to the hydraulic cycle, press SERVICE from the **MAIN MENU**, then press MECHANICS

• Operators must be trained and to know that due to moving parts there is a risk to pinch their fingers between pistons and the syringe body



- Press LUBRICATION POS. to put the piston of the syringe module in the greasing position.

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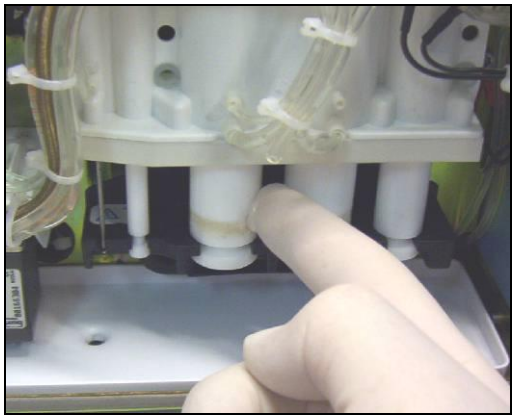
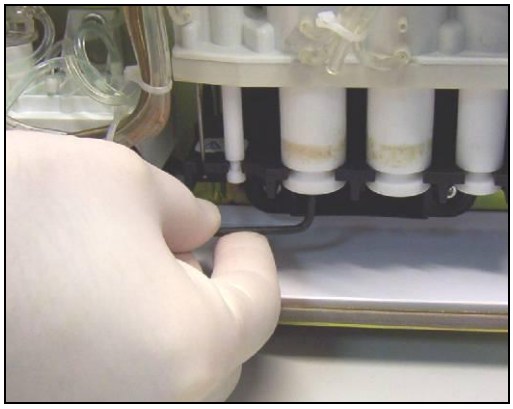
Wear rubber gloves and wash hands with a disinfectant after completion of work.

- Wait for the information window and then
- Open the door on the right side (see section 1.1.3).
- Put a small nut of grease on a finger.



- Put a thin film of grease around each piston.



- Turn the two big pistons (waste pistons) with the help of the key supplied in the installation kit.
- Continue to put a thin film of grease around each piston.
- The other pistons can be turned with fingers.

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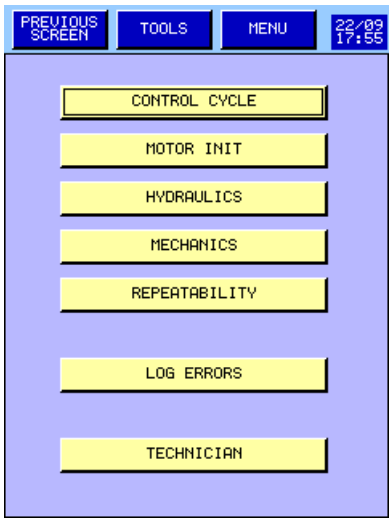
9.2 HYDRAULIC CYCLES



- To have access to the hydraulic cycle, press SERVICE from the **MAIN MENU**, then press HYDRAULICS

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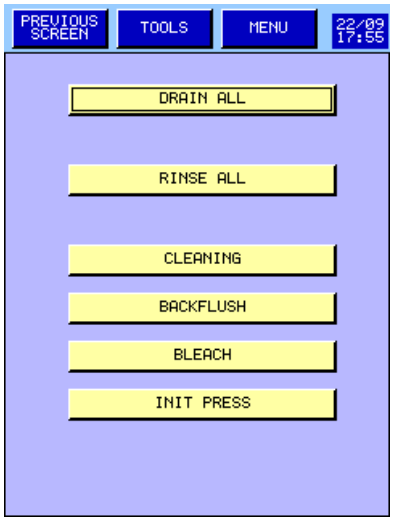


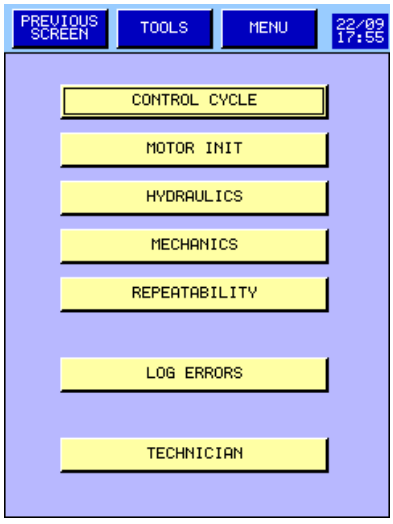
- To drain the counting baths and the waste syringes, press DRAIN ALL

- To fill the counting baths with 2 ml of diluent, press RINSE ALL

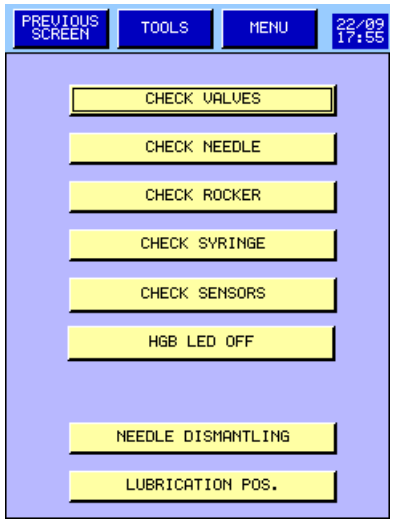
- To perform a cleaning of the aperture block with the cleaner, press CLEANING

- To perform a back flush in the aperture blocks, press BACKFLUSH

9.3 MECHANICS



- To have access to this cycle, press SERVICE from the **MAIN MENU**, then press MECHANICS



CHECK VALVES See below.

CHECK NEEDLE Performs a complete test of the needle.

CHECK ROCKER Performs a complete test of the rocker.

CHECK SYRINGE Performs a complete test of the syringe.

CHECK SENSORS Enables to check the different sensors.

HGB LED OFF Switches on (or off) the led to check it.

NEEDLE DISMANTLING See section 9.4.2

LUBRICATION POS. See section 9.1.3

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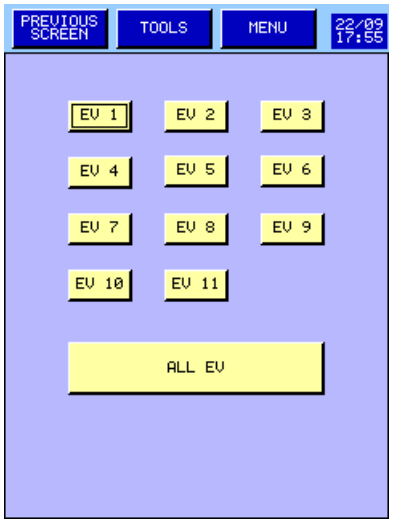


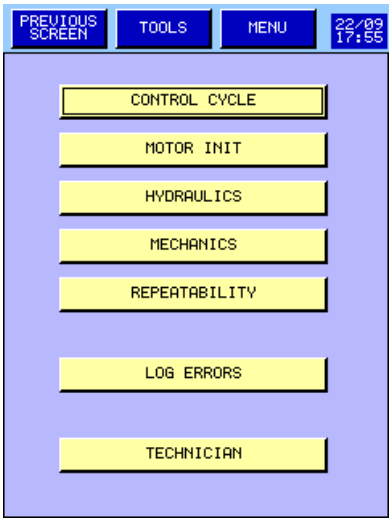
- To test each valve, press the dedicated button.

- To test all the valves press

9.4 REPAIRING

9.4.1 Emergency stop

In case of mechanical or hydraulic problem, immediately press , the **MYTHIC 18** will make an emergency stop.



- After having identified the problem, it is necessary to perform a Control cycle.

- To have access to this cycle, press

from the **MAIN MENU**, then press

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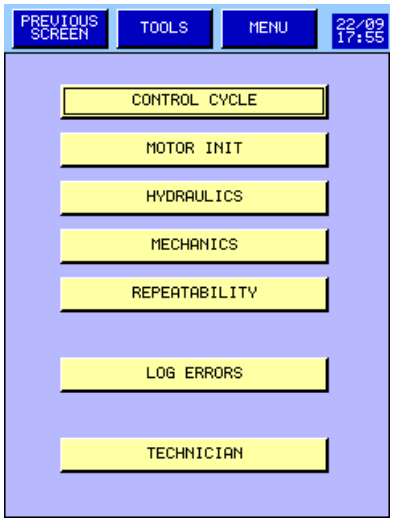
9.4.2 Needle or o-ring replacement

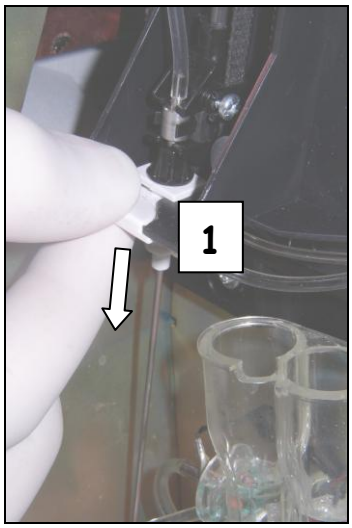
	Wear rubber gloves and wash hands with a disinfectant after completion of work.



- From the main menu, press SERVICE then MECHANICS to go to the display described on the left.
- Press on NEEDLE DISMANTLING
- The rocker places the sampling needle in the disassembling position.
- Open the door located on the right side to have access to the hydraulic part.

Wait for the information window and then open the door.

- The needle is in front of the counting chambers



- Remove the sampling module, while slightly lowering the clip 1 to the bottom.

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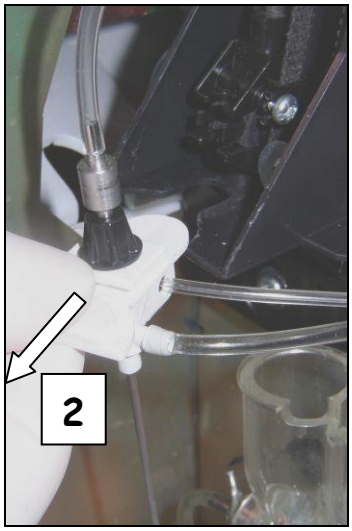
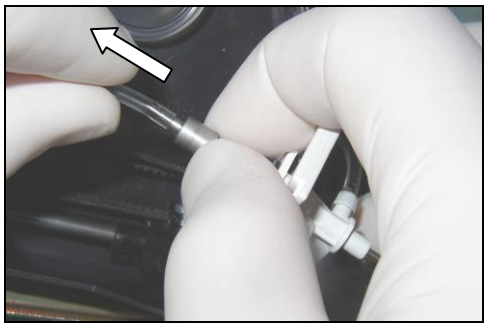
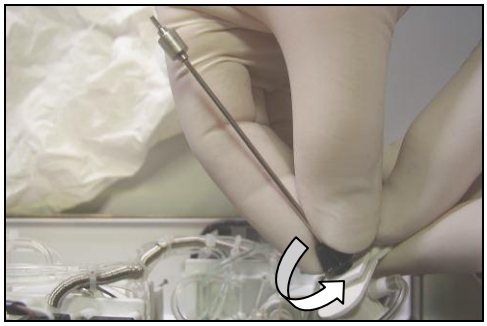


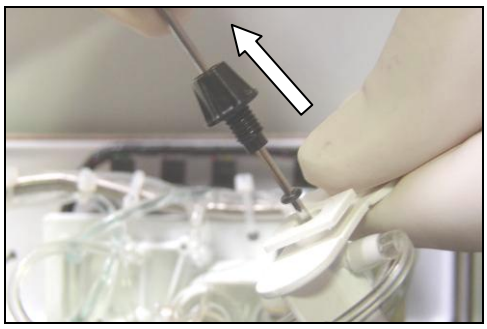
- Draw the system towards outside **2** .



- Remove the tubing fixed at the end of the needle.



- Unscrew the serrated roller which maintains the seal and the needle.



- Leave the serrated roller, the needle and the o-ring from the rinsing head.

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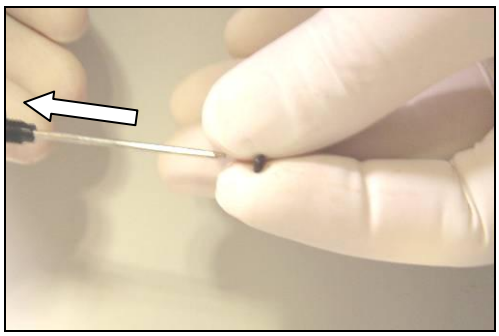


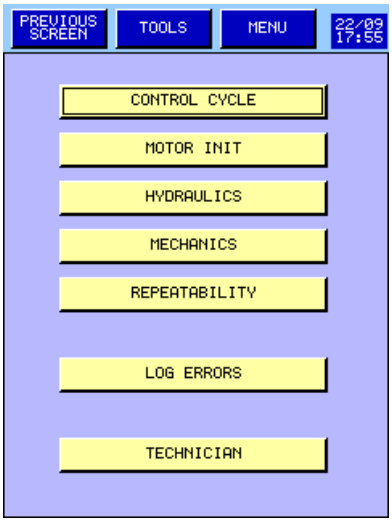
- Remove the o-ring.
- Replace the needle with or the o-ring.

REASSEMBLY PROCEDURE:
To reassemble the unit, carry out the various operations in the opposite direction. Place the seal on the needle gently not to wound it.

9.4.3 Baths dismantling

This procedure must be carried out to replace the bath seals on the manifold or the aperture seals.

	Wear rubber gloves and wash hands with a disinfectant after completion of work.



- From the **MAIN MENU**, press SERVICE then press HYDRAULICS.

- Press DRAIN ALL to perform a draining of the counting baths.

- Open the door located on the right side of the instrument to have access to the hydraulic part.

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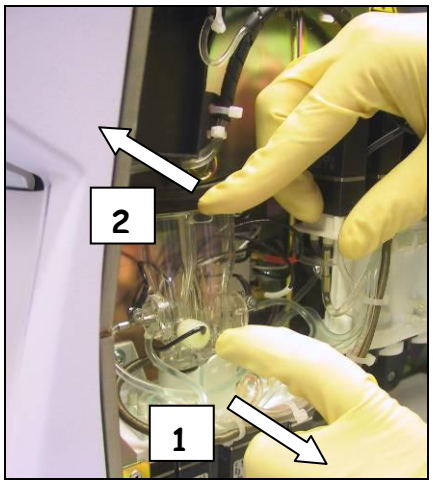
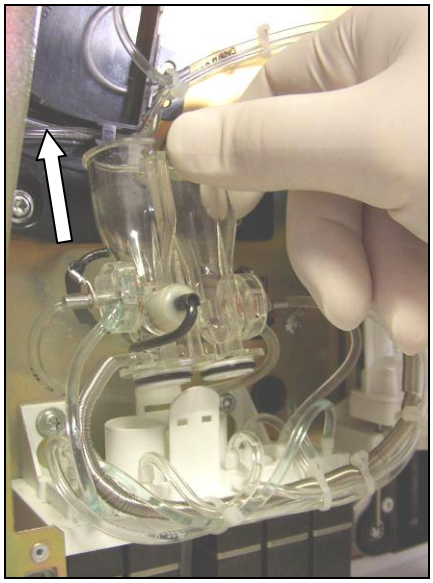
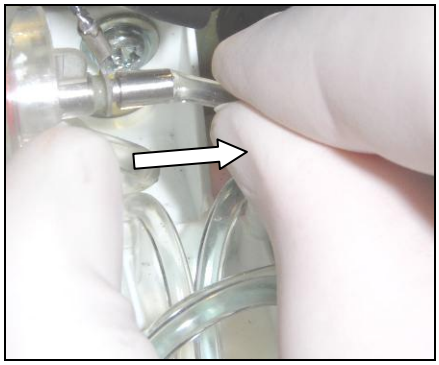


- To remove the counting bath module, **very carefully and slowly**, draw on the clip **1** while pushing the top from the counting bath towards the inside of the machine **2**.



- Then, upwards, raise the counting module.



- Next, remove the tubing fixed on the RBC counting head, located on the right side of the counting module.

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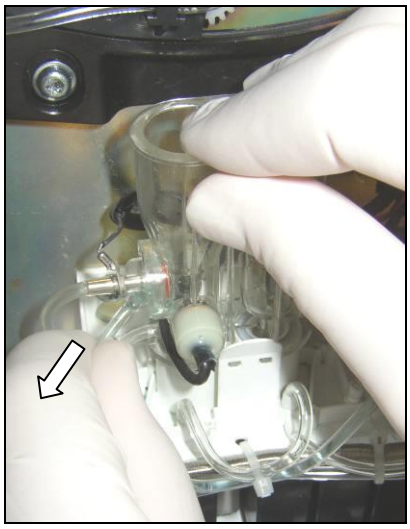
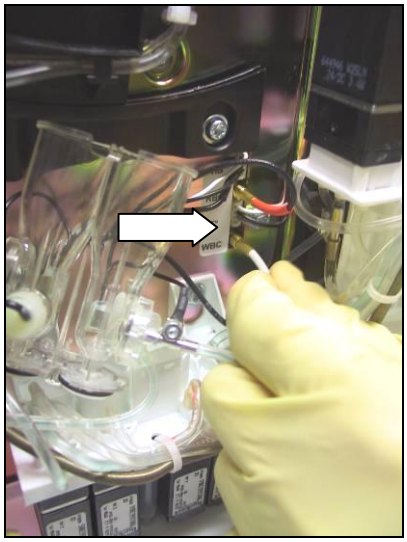


- Remove the tubing fixed on the plastic fitting located under the stainless tube from WBC counting block.



- Remove all connectors.

- The counting bath module can now be handled to carry out the desired operations of replacement.

REASSEMBLY PROCEDURE:

To reassemble the unit, carry out the various operations in the opposite direction.

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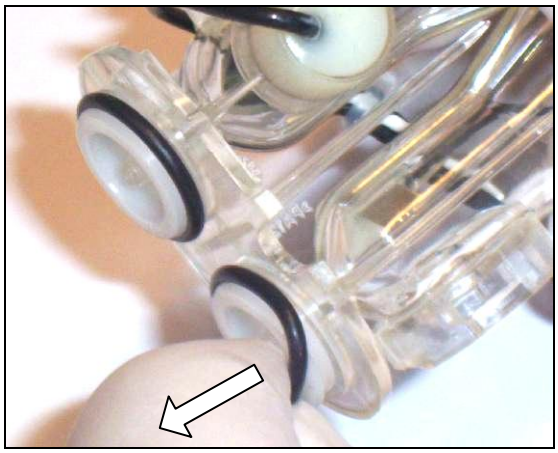
9.4.4 Baths o-ring replacement

	Wear rubber gloves and wash hands with a disinfectant after completion of work.



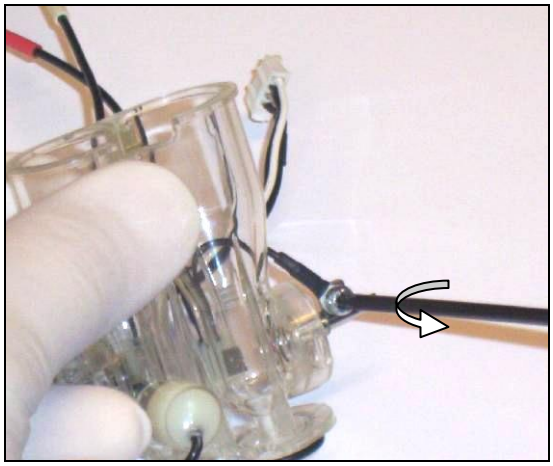
- Before performing the operation, drain the baths and dismantle the counting bath block (see section **9.4.3**).

- Replace the o-ring and/or the complete bath block.

REASSEMBLY PROCEDURE:
To reassemble the unit, carry out the various operations in the opposite direction.
Place the seal on the counting bath gently not to wound it.

9.4.5 Aperture block replacement

	Wear rubber gloves and wash hands with a disinfectant after completion of work.

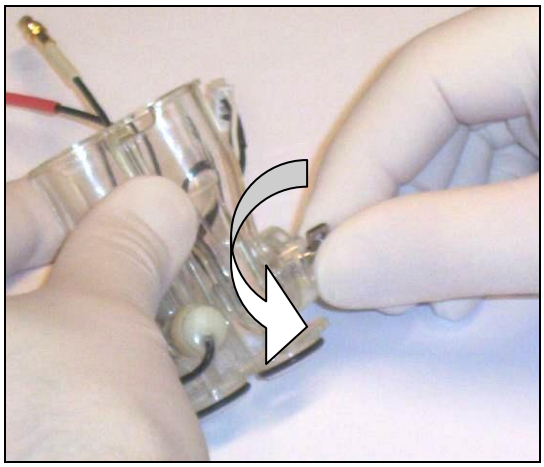


- Before performing the operation, drain the baths and dismantle the counting bath block (see section **9.4.3**).

- Remove the tubing from the blocks to be replaced.

- With the help of the provided tool in the maintenance kit, unscrew the screw and remove the connection.

NOTA: This operation can be performed without dismantling the complete bath block.



- Unscrew the aperture block of a quarter of turn.

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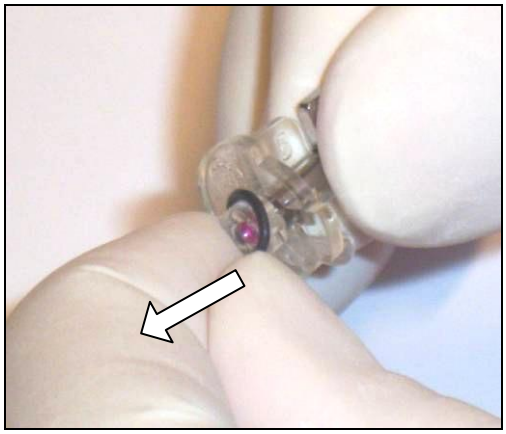

- Remove the o-ring and replace by a new one or replace the whole part.

NOTA: The WBC aperture block is marked with a figure **8** on the ear and with a figure **5** for the RBC.

REASSEMBLY PROCEDURE:

To reassemble the unit, carry out the various operations in the opposite direction.
Place the seal on the aperture block gently not to wound it.

9.5 TROUBLESHOOTING

In any case, if a problem is not solved, call Orphée's representative.

9.5.1 Analytical problems

PARAMETERS	PROBLEMS	CONDITIONS	SOLUTIONS
WBC	No results	No HGB	Check the bath wires. Check the lysis level. Check the right lysis tubing connection to the WBC bath.
		HGB OK	Check the bath wires. Perform a Cleaning Cycle and then a Bleach cycle if unsuccessful.
	Bad stability		Perform a Back flush and a Cleaning Cycle and then a Bleach cycle if unsuccessful. Check the level bubble flow in the WBC bath during the run cycle.
RBC	No results	No HCT & PLT	Check the bath wires. Perform a Cleaning Cycle and then a Bleach cycle if unsuccessful.
	Bad stability	HCT & PLT too	Perform a Back flush and a Cleaning Cycle and then a Bleach cycle if unsuccessful. Check the level bubble flow in the RBC bath during the run cycle. Check the level bubble flow in the WBC bath during the first dilution.
HGB	No results		Check the led light on.
	Bad stability		Check if no bubble in the lysis tubing. Check the level bubble flow in the WBC bath during the run cycle.
	Rejection	--- *	Close the door. Perform a new Start Up cycle.

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9.5.2 Other problems

ORIGIN	PROBLEMS	SOLUTIONS
MYTHIC	Diluent leaks around the needle during the run cycle	Check the rinsing needle block (presence of clots) and clean it if necessary see section 9.4.2
	No starting	Check the power supply connection wires.
	All results bad	Check the level diluent and if the supply tubing is pinched. Check if the diluent is placed at the same level as the MYTHIC 18
	No display	Check the flat cable.
	ID and/or PID typing impossible	ID and/or PID are mandatory (see section 3.4.3).
	Message : cycle : pressure default or Flag INS_P	Check the level of the reagents; check the tubing connection of the fluidics.
Printer	No printing	Check the paper. Check the electrical connection.
	Bad printing	Check the black ribbon.

9.6 TROUBLESHOOTING MESSAGE

This section allows knowing what to do when a troubleshooting message appears on the screen.
In any case, if a problem is not solved, call Orphée's representative.

MESSAGE	ACTION
BACKUP : FOLDER NOT FOUND	Re-start the Mythic.
BACKUP: BAD FOLDER DUPLICATION	Re-start the Mythic
BACKUP: CALIBRATION HISTORY IS FULL	Delete the calibration results.
BACKUP: FAIL TO SAVE RESULT ONTO THE EXTERNAL STORAGE DEVICE. THE INTERNAL MEMORY IS USED.	Please connect USB thumb drive to the analyzer
BACKUP: FILE SYSTEM FAILED.	Re-start the Mythic.
BACKUP: LAST RESULT SAVED.	Memory full, next result will not be saved. You have to delete results.
BACKUP: MEMORY IS ALMOST FULL. PLEASE DELETE RESULTS.	Delete results
BACKUP: NO MEMORY AVAILABLE FOR STORAGE	Delete the stored results.
BACKUP: QC HISTORY IS FULL	Delete the Q.C. results of the ongoing lot.
BACKUP: REPEATABILITY HISTORY IS FULL	Delete the repeatability results.
BACKUP: SECTOR FAILED.	hardware failure on memory
BACKUP: SYSTEM ERROR	Re-start the Mythic.
CLEAN NOT DONE	Perform a rinse cycle.
CLEANER ALMOST EMPTY	Replace the bottle and perform a prime Cleaner
COM: BAD CYCLE MODULE	Rebuild cycles with good options
COM: CRC CONTROL ERROR	Communication error retry
COM: SIZE ERROR.	Try to send the file again If the problem still occurs, call an Orphée representative.
CONTROL CYCLE NOT DONE	Perform a control cycle.
CYCLE STOPPED BY USER	Emergency stop, please perform a control cycle.

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MESSAGE	ACTION
CYCLE: BUSY	Wait before performing a cycle.
CYCLE: CMD VALVE FAILED	Change the valve
CYCLE: EMERGENCY STOP	Perform a control cycle.
CYCLE: FLUIDIC DOOR OPENED	Close the door, in case of emergency stop run a control cycle
CYCLE: HGB CHANNEL SATURATION. PLEASE RUN STARTUP.	Run Startup Cycle. If the problem still occurs, call an Orphée representative.
CYCLE: INIT NOT DONE	Perform an initialization or a control cycle.
CYCLE: PRESSURE DEFAULT	May occurred by leak of reagent, check tubing in the fluidics
CYCLE: VALVE XX FAILED	Change the valve
DILUENT ALMOST EMPTY	Replace the container and perform a prime Diluent
HARDWARE: SYSTEM ERROR	Re-start the Mythic.
HEATING IN PROGRESS, PLEASE WAIT.	Wait for the system to reach its temperature
ID AND/OR PID MANDATORY (CHECK SETUP). SID ALWAYS MANDATORY.	Enter an ID and/or PID and SID
INIT PRINTER	Switch on the printer or invalidate the printings.
INTERN: COUNT ERROR	Re-start the Mythic.
INTERN: MEMORY CORRUPTED	Re-start the Mythic.
INTERN: NO MEMORY AVAILABLE	Re-start the Mythic.
INTERN: RESULT AREA IS LOCKED	Wait before performing a cycle. If persisting, re-start the Mythic.
INVALID DATA FORMAT.	The files format are not available for the Mythic
LOT ALREADY EXISTS. ACTION CANCELLED.	Select other lot
LYSE ALMOST EMPTY	Replace the bottle and perform a prime Lysis
MECA: HOME NEEDLE NOT FOUND	Perform an initialization or a control cycle.
MECA: HOME ROCKER NOT FOUND	Perform an initialization or a control cycle.
MECA: HOME SYRINGE NOT FOUND	Perform an initialization or a control cycle.
MECA: MOTOR NEEDLE BUSY	Re-start the Mythic.
MECA: MOTOR ROCKER BUSY	Re-start the Mythic.
MECA: MOTOR SYRINGE BUSY	Re-start the Mythic.
MECA: MOTOR SYRINGE GAP	Perform a pistons greasing
MECA: NEEDLE NOT IN TOP POSITION	Perform a control cycle.
NETWARE: SERVER INIT. FAILED	Call an Orphée representative.
NETWARE: CLIENT INIT. FAILED.	Call an Orphée representative.
NO PRINTER RESPONSE	Switch on the printer or invalidate the printings.
NO PRINTER SELECTED	Switch on the printer or invalidate the printings.
NO PRINTER SELECTED	Switch on the printer or invalidate the printings.
NUMBER MAX. OF FILES REACHED. PLEASE DELETE FILES.	Delete some files
OUT OF RANGE	Modify the value
PRINTER DRIVER UPDATE FAILED. THE CHOSEN DRIVER IS NOT COMPATIBLE WITH THE MYTHIC 22 SYSTEM.	Select the correct version
PRINTER ERROR	Switch on the printer or invalidate the printings.
PRINTER IS BUSY	Switch on the printer or invalidate the printings.
PRINTER IS OFF	Switch on the printer or invalidate the printings.
PRINTER: NO PAPER	Add some paper.
RINSE NOT DONE	Perform a clean cycle.
RS232: ACK ERROR	Re-start the Mythic.
RS232: INTERNAL ERROR	Re-start the Mythic.

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MESSAGE	ACTION
RS232: SYNCHRO ERROR	Re-start the Mythic.
RS232: TIME OUT	Re-start the Mythic.
RUNNING AUTO CLEANING	Press OK.
SETUP: MODIFICATION NOT ALLOWED.	You have to be Logged with the good access code
START UP CYCLE NOT DONE	Perform a start up cycle.
STARTUP CYCLE FAILED	Perform a new start up cycle
SVM: BAD VERSION	Update the SVM software
SVM: COM. TIME OUT	Re-start the SVM.
SVM: ILLEGAL SERIAL NUMBER.	This MYTHIC cannot be connected to the SVM
SVM: UNMATCH	Re-enter the file or confirm it (manual connection on the SVM).
SVM: WG	Westgard alarm.
SVM: XB	XB alarm.
SYSTEM LOCKED HEATING FAILED	Call an Orphée representative.
SYSTEM: DOWNLOADING NEW VERSION. PLEASE WAIT	System is resetting after version release
SYSTEM: EEPROM COM ERROR	Re-start the Mythic.
SYSTEM: FATAL ERROR	Re-start the Mythic.
SYSTEM: INTERNAL TIME OUT	Re-start the Mythic.
THE CLEANER USED IS OUT OF DATE.	Replace the bottle and perform a prime Cleaner
THE DILUENT USED IS OUT OF DATE.	Replace the container and perform a prime Diluent
THE LYSE USED IS OUT OF DATE.	Replace the bottle and perform a prime Lysis
USB: DIRECTORY DOES NOT EXIST.	Try again or change for another USB Thumb.
USB: DIRECTORY IS NOT EMPTY.	Try again or change for another USB Thumb.
USB: EMPTY FILE	Try again or change for another USB Thumb.
USB: THUMB DRIVE I/O ERROR	Try again or change for another USB Thumb.
USB: THUMB DRIVE IS FULL.	Delete some files
USB: THUMB DRIVE IS NOT PRESENT.	Please connect USB thumb drive to the analyzer
USB: TOO MANY FILES OPENED.	Delete some files
USB: UNABLE TO CREATE DIRECTORY.	Try again or change for another USB Thumb.
USB: UNABLE TO OPEN DIRECTORY.	Try again or change for another USB Thumb.
USB: UNABLE TO OPEN FILE	Try again or change for another USB Thumb.
USB: WRITE PROTECTED FILE.	Try again or change for another USB Thumb.
VERSION RELEASE FAILED. THE CHOSEN RELEASE IS NOT COMPATIBLE WITH THE MYTHIC 22 SYSTEM.	Select the correct version
WASTE ALMOST FULL	Replace the waste container

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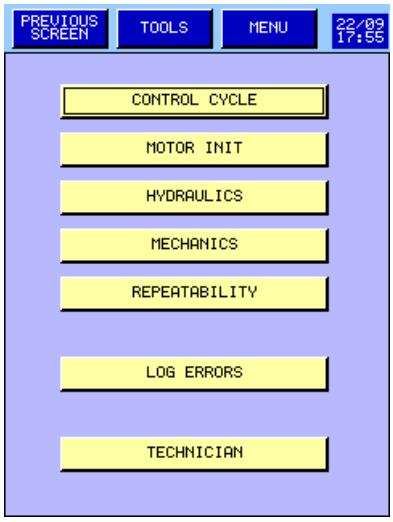
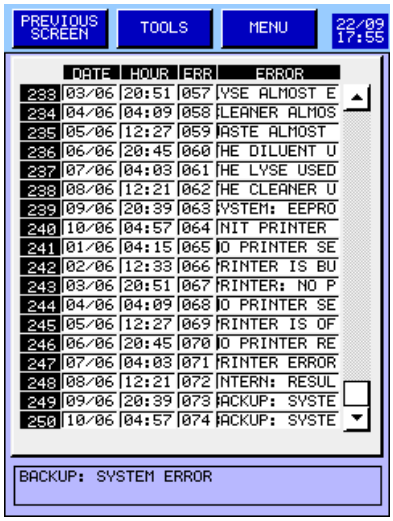
9.7 LOGS ERRORS



- From the MAIN MENU press SERVICE .

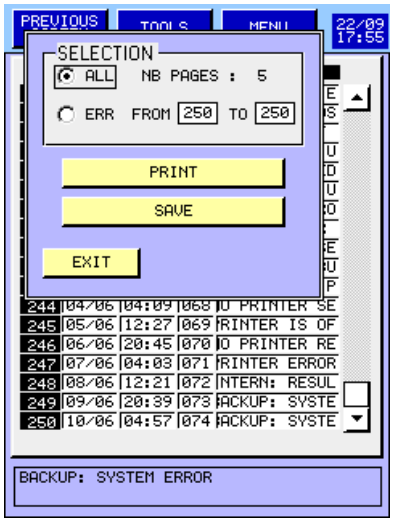
- Then press LOG ERRORS



- This screen allows visualizing the date and timing when an error has occurred, as well as the code and the origin of this error.

- To see the origin of the error, press on the figure located on the left of the date, the complete error appears at the bottom.

- To print it press TOOLS .



- Select ALL to print the errors of the number of pages indicated on the screen.
- To print or save (in an USB key) the error of one or more days select ERR FROM 250 TO 250 then enter the error reference number.

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9.8 HYDRAULIC DIAGRAM

The length and inner diameters of the tubing shown on the diagram below the tubing table must be strictly respected when replaced; otherwise there is a significant risk in the quality of results given.

		tubing 0,8x2,4mm	tubing 1,3x3mm	tubing 1,6x3,2mm	tubing 2x4mm	tubing 3x6mm
Part Number	**Designation**					
005-1001-90 01	Tubing 1			820+180mm		
005-1001-90 02	Tubing 2			250mm		
005-1001-90 03	Tubing 3				135+20mm	
005-1001-90 04	Tubing 4				175+15mm	
005-1001-90 05	Tubing 5				210mm	
005-1001-90 06	Tubing 6				170mm	
005-1001-90 07	Tubing 7			220mm		
005-1001-90 08	Tubing 8			80mm		
005-1001-90 09	Tubing 9		425mm			
005-1001-90 10	Tubing 10	370mm			8mm	
005-1001-90 11	Tubing 11				90mm	
005-1001-90 12	Tubing 12			60mm		
005-1001-90 13	Tubing 13			250mm		
005-1001-90 14	Tubing 14			250mm		
005-1001-90 15	Tubing 15			1000mm		
005-1001-90 16	Tubing 16			130mm		
005-1001-90 17	Tubing 17			80mm		
005-1001-90 18	Tubing 18			80mm		
005-1001-90 19	Tubing 19			80mm		
005-1001-90 20	Tubing 20			130mm		
005-1001-90 21	Tubing 21			600mm		
005-1001-90 22	Tubing 22		200mm			
005-1001-90 23	Tubing 23 - DILUENT					1500mm
005-1001-90 24	Tubing 24 - WASTE					1500mm

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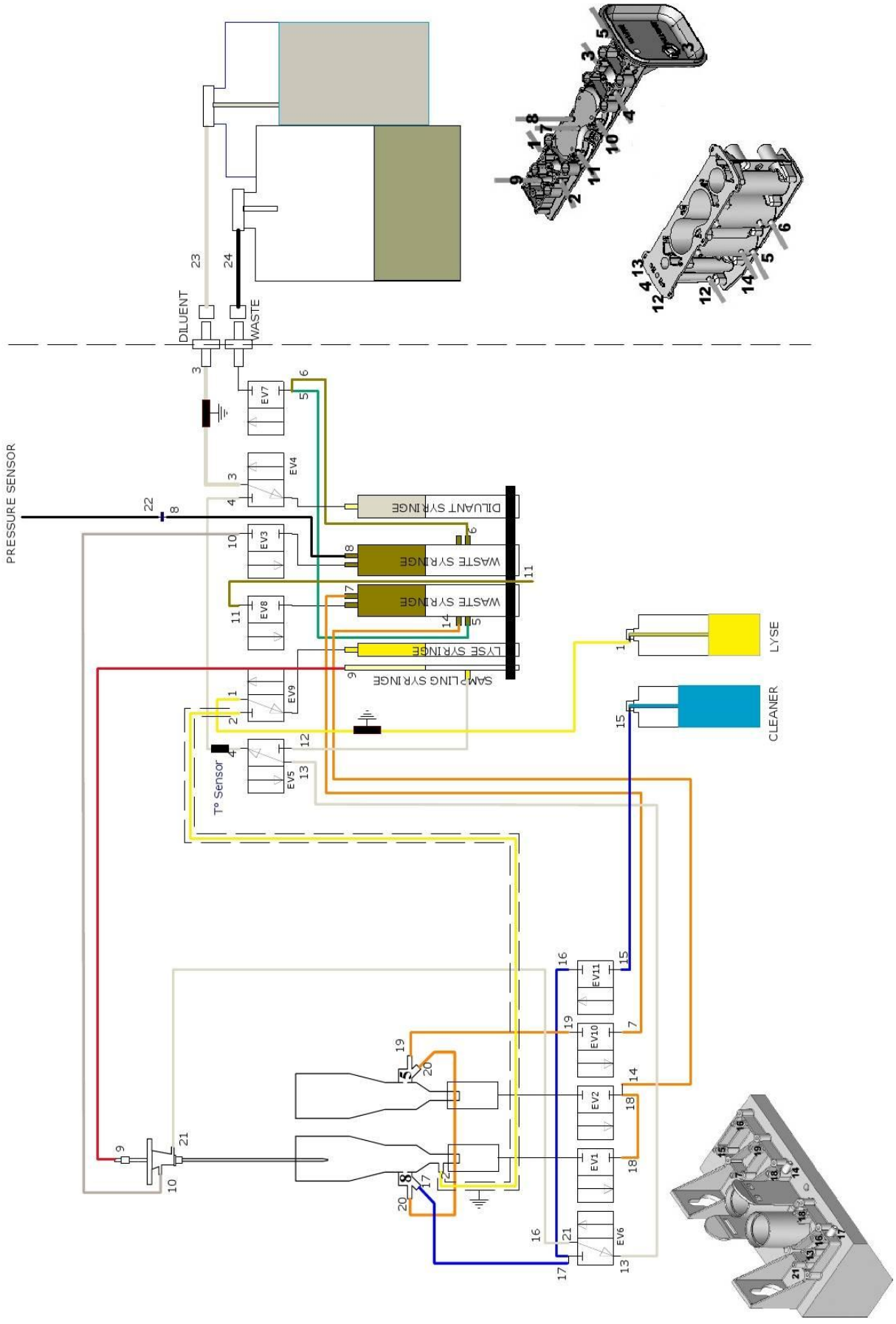

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